UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.,
Case No. 18-op-45090

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.,
Case No. 17-op-45004

MDL No. 2804

Case No. 1:17-md-2804

Judge Dan Aaron Polster

***Corrected* Defendants' Response to Plaintiffs' Motion for Partial Summary Adjudication on Defendants' Compliance With the Controlled Substances Act [CSA Compliance Brief]**

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INTRODUCTION

Plaintiffs ask the Court to rule now, without a trial, that 16 Defendants violated the Controlled Substances Act (CSA). *See* Dkt. 1910 (Br.) at 1. Plaintiffs' motion is wrong on the law. It is also riddled with disputed facts that preclude summary judgment.

First, Plaintiffs' motion is based on the notion that the CSA imposes "duties" the Court can enforce, including a duty "to refrain from shipping orders flagged as 'suspicious' unless it has been determined that the order is not likely to be diverted." Br. at 1. As explained in Defendants' separate response to Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties under the CSA (Defs. CSA Duties Br.), no such duties exist under the CSA. Nor can DEA impose duties on registrants through informal guidance. But even assuming DEA's informal guidance is relevant, it cannot be applied retroactively. The record shows that Defendants modified their suspicious order monitoring (SOM) systems over time to come in line with DEA's changing expectations. At a minimum, the facts are disputed.

Second, Plaintiffs say Defendants failed to "maintain effective controls against diversion." Br. at 1. This, too, is hotly disputed. Among other things, there is no diversion in Cuyahoga and Summit Counties connected to Defendants. ***None***. Plaintiffs' SOM expert did not even "look at any particular order to see whether it was diverted." Rafalski Tr. 508:1-12 (Dkt. 1969-19/1983-16). "I don't have any direct knowledge of what happened to any of the drugs that were distributed to each of the pharmacies. I didn't conduct any analysis as of today that would give me that knowledge." *Id*. 582:9-19. All Plaintiffs have shown is that Defendants shipped opioids that filled legitimate prescriptions—in volumes approved by DEA to meet legitimate medical needs. Plaintiffs have come nowhere near meeting their burdens of proof and persuasion. With no evidence of diversion, Plaintiffs' motion must be denied.

Third, Plaintiffs seek to prove their claims through alleged CSA "violations," but the law forbids private enforcement of the CSA. Moreover, proof of such "violations" will not remove claims or Defendants from the case. It will not establish any element of any of Plaintiffs' state law claims. Nor will it satisfy Plaintiffs' burden under RICO to identify and prove the specific predicate acts committed by each Defendant that allegedly caused them harm. For these reasons, too, Plaintiffs' motion should be denied.

BACKGROUND

Congress enacted the CSA in 1971 to regulate the manufacture and distribution of controlled substances. The CSA establishes a closed system of distribution, and every manufacturer, distributor, pharmacy, and prescriber in the supply chain must register with DEA. 21 U.S.C. § 822(a). DEA's approval of a registrant's application allows others within the closed system to rely on that DEA registration.[1]

A. DEA Controls How Many Opioids Are Manufactured Each Year.

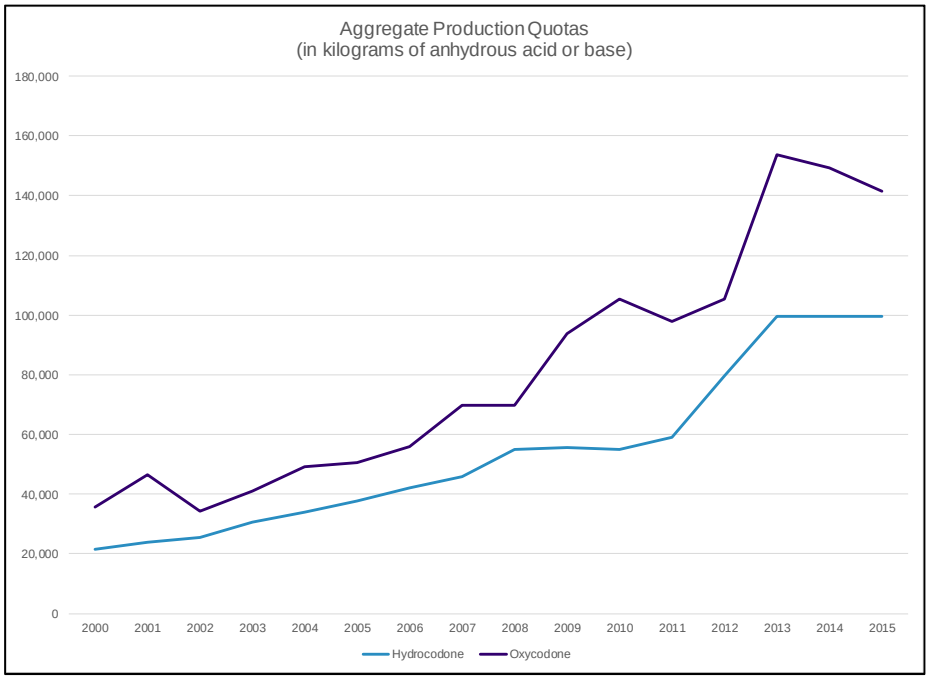
Plaintiffs decry the volume of opioids sold in their counties. Br. at 1. But at a minimum, there is a fact dispute about how many opioids should have been sold. DEA limits how many controlled substances are sold in the United States by setting annual quotas. 21 C.F.R. § 1303.11. DEA's former head of the Office of Diversion Control, Joseph Rannazzisi, has explained, "in the case of the most potentially dangerous drugs, in Schedule II, we register all persons who handle them; we inspect the documentation of their distribution; we control their

[1] 21 C.F.R. § 1301.74(a); *see* Rafalski Tr. 386:18-387:4 (Dkt. 1969-18/1983-15). On first reference, citations to expert reports and deposition transcripts that have been filed on the docket include the docket numbers (both sealed and public versions, respectively). Appendix A is a cross-reference chart of all such expert reports and transcripts.

import and export; and ***we control the amount produced, bought, sold, and otherwise transferred***."[2]

DEA is required to set its annual quotas based on its determination of legitimate medical need in the United States.[3] Over the past two decades, if DEA had determined that too many opioids were being sold—and particularly if it had believed that the large volumes of opioids being prescribed were not for legitimate medical needs, but were being diverted—DEA could have, and should have, reduced its quotas. DEA has done so in the past for other drugs.[4] But DEA increased opioid quotas "constantly" and "significantly" in the relevant time period:[5]

Figure 1: DEA Quotas for Oxycodone and Hydrocodone (2000-2015)



[2] Ex. 1 July 26, 2006 Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? at 68 (emphasis added).
[3] *See* 21 C.F.R. § 1303.11; Harper-Avila Tr. 113:11-114:16 (Dkt. 1962-20/1977-25).
[4] *See* Ex. 2 Nicolas Rasmussen, PhD, MPhi, MPH, *America's First Amphetamine Epidemic 1929-1971, A Quantitative and Qualitative Retrospect with Implications for the Present*, 98 Am. J. of Pub. Health, 974 at 980 (June 2008); see also Ex. 3 Larry Cote, *Opinions, The Real History of the DEA and Opioids*, Washington Post (Dec. 1, 2017) https://www.washingtonpost.com/opinions/the-real-history-of-the-dea-and-opioids/2017/12/01/6ab9d194-d5f7-11e7-9ad9-ca0619edfa05_story.html?utm_term=.5366af41f6ca.
[5] Rannazzisi Tr. 31:5-19, 31:25-33:23 (Dkt. 1969-20/1983-17). *See also* Ex. 4 Jan. 13, 2010 Aggregate Production Quota History; Ex. 5 Jan. 22, 2019 Aggregate Production Quota History.

Not only does DEA set quotas based on legitimate medical need, the responsibility "for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner" who writes the prescription. *See* 21 C.F.R. § 1306.04(a). A corresponding responsibility rests with the pharmacist to fill legitimate prescriptions. *See id.* Distributors, in turn, supply the orders to meet those legitimate needs. Plaintiffs' own experts acknowledge most opioid prescriptions are written legitimately, and that rogue doctors and pill mills did not contribute significantly to abuse.[6] And Plaintiffs have failed to identify orders that were unlawfully diverted. All they can show is that Defendants manufactured and shipped orders to fill legitimate prescriptions at volumes DEA deemed appropriate.

B. DEA Has Unique Law Enforcement Powers to Fight Diversion.

Plaintiffs assert that the "system does not rely on the DEA to police shipments of controlled substances." Br. at 4. This is flat wrong. At a bare minimum, it is disputed. DEA has expansive enforcement powers to fight diversion—powers registrants simply do not have.[7] For decades, DEA has maintained vast amounts of data in its ARCOS database, showing every opioid manufactured and sold in the United States.[8] DEA relies on ARCOS data to prevent diversion, but "does not share unredacted ARCOS information with the public."[9] DEA can issue subpoenas and search warrants, compel witness testimony, and conduct undercover investigations, including by wiretapping phones.[10] DEA also can obtain information about registrants and potential diversion from state law enforcement and medical boards.[11]

[6] *See* Lembke Tr. 223:25-224:15 (Dkt. 1966-2/1979-17); Schumacher Rpt. ¶ 60 (Dkt. 2000-24/1999-23).
[7] Ex. 6 Mapes Tr. 266:6-13.
[8] Mapes Tr. 292:1-23, 293:14-294:2; Prevoznik 30(b)(6) Tr. 508:16-23, 511:5-514:4 (Dkt. 1969-13/1983-10); Wright Tr. 121:22-122:20 (Dkt. 1972-12/1985-24); Ex. 7 Feb. 26, 2019 DEA Press Release.
[9] July 26, 2019 DEA Decl. of Joey Lenseigne (Dkt. 2040-1 at 3).
[10] Mapes Tr. 266:15-268:19, 270:8-18, 272:13-17, 274:21-275:5, 275:16-25, 277:24-278:11, 281:3-13.
[11] Mapes Tr. 285:13-286:1.

C. DEA Controls Who Manufactures, Distributes, and Dispenses Opioids.

The CSA charges DEA with the responsibility for registering manufacturers and distributors of controlled substances in a manner consistent with the "public interest." 21 U.S.C. § 823. Among the factors that DEA must consider before granting or renewing a registration is whether the manufacturer or distributor maintains "effective controls against diversion." *Id.* Under the CSA's implementing regulations, DEA must evaluate "the overall security system and needs of the applicant or registrant." 21 C.F.R. § 1301.71(b). One of several security requirements DEA takes into account is whether the registrant has designed and operated a system to disclose "suspicious orders" to itself, and to inform DEA of those orders "when discovered." 21 C.F.R. §§ 1301.71(a), 1301.74 (b).[12]

DEA is empowered to suspend or revoke a manufacturer's or distributor's registration under circumstances specified in the CSA. *See* 21 U.S.C. § 824. In evaluating registrants, DEA imposes a "substantial compliance" standard. 21 C.F.R. § 1301.71(b).

D. For Decades, DEA Accepted Reports of Suspicious Order After Shipping.

Plaintiffs assert that Defendants have always been required to inform DEA of suspicious orders before shipping them. Br. at 5. This, too, is—at a minimum—disputed. For roughly forty years, DEA understood and endorsed distributors' practice of submitting information about "excessive" or "potentially suspicious" purchases to DEA, ***after those orders were shipped***.[13] DEA guidance dating back to at least 1998, and available on DEA's website until 2013,

[12] The regulations define "suspicious orders" as "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

[13] Wright Tr. 72:4-10 ("Q. Okay. And prior--through 2005, did you understand that it was standard practice in the industry to submit Excessive Purchase Reports while continuing to ship product? … A. Yes, ma'am."); *id*. 72:12-16, 75:2-9; Mapes Tr. 93:21-94:3 ("Q. And in the course of your role as a diversion investigator and a group supervisor, you accepted these excessive purchase reports as compliant with the Controlled Substances Act? … A. Yes."), *id*. 92:1-97:18, 227:12-228:2, 518:7-521:18; Ashley Tr. 30:18-31:4 (Dkt. 1956-7/1974-7). *See* Mapes Tr. 92:1-95:17, 234:12-235:2, 519:4-521:18; Wright Tr. 72:4-10, 72:12-16, 75:2-9; Ashley Tr. 30:18-31:4.

contemplated doing just that: "At the end of each month, a report will be transmitted to DEA … of all purchases."[14]

E. Design of Suspicious Order Monitoring Systems Is Left to the Registrant.

Plaintiffs recite a laundry list of purported requirements for SOM systems. Br. at 17-18. Again, these are disputed. The regulations leave the design of a SOM program to the registrant's discretion.[15] DEA considers this to be a "business decision" based on the registrant's business model and customer base.[16] DEA acknowledges that it is up to the registrant to determine what constitutes a "suspicious order" and how to inform DEA of suspicious orders.[17] As DEA's 30(b)(6) witness testified, "there's more than one way to design and operate a system that can identify and report suspicious orders."[18] DEA has provided no guidance on the meaning of "unusual size," "deviating from a normal pattern," or "unusual frequency."[19] And DEA recognizes that "suspicious orders" are not necessarily orders that will be diverted—they may well sit on a pharmacy shelf until they are dispensed via a legitimate prescription.[20]

F. DEA Worked With Distributors and Approved Early SOM Systems.

Given the lack of formal guidance governing SOM systems, DEA worked with certain distributors during the 1990s to develop programs that were then approved by DEA.

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[14] *See* Ex. 8, Suspicious Orders Task Force Report at A:4 ("At the end of each month, a report will be transmitted to DEA (separate reports for List I Chemicals and Schedule II – V Controlled Substances) of all purchases of List I Chemicals and/or C-II-V Controlled Substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above)."); Ex. 9 March 2013 DEA Office of Diversion Control Webpage (WAGMDL00400361).
[15] *See* Rannazzisi Tr. 321:8-322:9; Prevoznik 30(b)(6) Tr. 179:22-180:2 (Dkt. 1969-12/1983-9); Ashley Tr. 88:2-10 (DEA requires no particular algorithm or method for identifying suspicious orders).
[16] Rannazzisi Tr. 42:24-43:9.
[17] *See* Prevoznik 30(b)(6) Tr. 179:22-180:2.
[18] Prevoznik 30(b)(6) Tr. 179:22-180:2.
[19] *Id.*; Ashley Tr. 26:1-27:13, 147:8-11; Mapes Tr. 80:14-81:6, 89:1-90:14.
[20] Mapes Tr. 151:19-152:2; Ashley Tr. 147:8-11; Prevoznik 30(b)(6) Tr. 281:22-282:12, 307:18-308:17; Wright Tr. 212:24-213:2.

For example, between 1996 and 1998, DEA approved a SOM program that ABDC and DEA developed together. ABDC's DEA-approved program involved a computer program that produced a summary "excessive purchase report" for DEA of any orders that exceeded the past four-month average by a specified amount.[21] Under this DEA-approved program, ABDC shipped the "excessive" orders before informing DEA about them.[22] The SOM systems of several other distributors, including Cardinal Health and McKesson, used similar programs.[23]

In 1998, DEA released a report recommending that these existing DEA-approved SOM programs for controlled substances be applied to other chemicals listed in DEA's regulations:

> The Suspicious Orders Task Force recommends: That those in the wholesale drug distribution supply chain who are able to use the ***DEA-approved Suspicious Order Monitoring System in use by wholesale drug distributors for controlled substances*** as enhanced by the Task Force in Appendix A, Exhibit II, for the reporting of potentially suspicious orders of listed chemicals including ephedrine, pseudoephedrine and phenylpropanolamine.[24]

In line with the earlier SOM systems DEA had approved, the Task Force recommended informing DEA of "excessive" or "suspicious" purchases using a threshold based on an average of purchase quantities, multiplied by a factor of three or eight, depending on the type of drug.[25] The Task Force noted, "Using a computer to manage and report on high volume transaction business activities with extremely short order cycles times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious." Ex. 12 at 2247. This guidance remained on DEA's website until 2013.[26]

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[21] Ex. 10, Sept. 30, 1996 Zimmerman Letter to DEA (ABDCMDL00269355 at 9356).
[22] *Id.*; Ex. 11, Oct. 29, 1996 DEA Letter to Zimmerman (ABDCMDL00315789 at 5789); *see also* Mapes Tr. 97:19-99:18, 101:18-103:5 (former DEA Investigator testifying that he separately approved an ABDC SOM system).
[23] *See* Rafalski Tr. 339:24-341:22; *see infra* Part II.A.1.
[24] Ex. 12, Oct. 1998 Suspicious Orders Task Force Report (CAH_MDL_PRIORPROD_HOUSE_002207 at 2230) (emphasis added).
[25] *See id.* Ex. II.
[26] *See* Ex. 9 at 4.

G. In 2005, DEA Began a Change in SOM Guidance.

Plaintiffs assert that DEA guidance on suspicious order monitoring has been consistent since the 1980s. Br. at 6-9. Defendants vigorously dispute the point. In fact, beginning in 2005, DEA guidance changed, precipitated by (1) DEA's Internet Distributor Initiative briefings targeting distribution to illegal internet pharmacies, and (2) two informal "Dear Registrant" letters, in 2006 and 2007, through which deputy assistant administrator Rannazzisi purported to impose entirely new requirements on distributors.[27]

DEA's 2005 "Distributor Initiative Program" involved individual meetings with distributors about the rise of rogue internet pharmacies.[28] Initially, DEA held meetings with less than a dozen distributors, and no chain pharmacies.[29] Indeed, DEA briefings noted that chain pharmacies were not "rogue pharmacies."[30]

On September 27, 2006, Rannazzisi issued his first "Dear Registrant" letter to the industry, reiterating guidance given during the distributor briefings about rogue internet pharmacies.[31] The second letter, dated December 27, 2007, announced for the first time DEA's newly minted "do not ship" and "know your customer" guidance.[32] These letters began the transition from DEA's former endorsement of "excessive purchase" systems to its new guidance that SOM programs be updated to include due diligence before shipping and to distinguish rogue

[27] Neither letter has been subject to notice-and-comment rulemaking. These letters do not have the force of law or properly describe registrants' CSA duties. *See* Defs. CSA "Duties" Br., Part II.D.1.
[28] Ex. 13, Aug. 16, 2005 Mapes Memo (US-DEA-00000147); Ex. 14, Oct. 20, 2005 Mapes Memo (MCKMDL00496859); Ex. 15, Aug. 23, 2005 Mapes Memo (US-DEA-00000352).
[29] Mapes Tr. 244:13-246:1.
[30] Prevoznik 30(b)(6) Tr. 480:21-481:12, 481:13-16 (identifying Walmart, CVS, Rite Aid, Walgreens, and HBC Giant Eagle as "chain pharmacies"); Ex. 16, Sept. 11, 2007 Pharmaceutical Industry Conference Recap at 4 (Presentation by DEA's Michael Mapes and ABDC's Chris Zimmerman "stressed the importance of knowing your customer, and providing due diligence investigations on all new retail and wholesale accounts, ***with the exception of retail chain pharmacies***") (emphasis added).
[31] Ex. 17, Sept. 27, 2006 Dear Registrant Letter (MCKMDL00478906 at 8908).
[32] Ex. 18, Dec. 27, 2007 Dear Registrant Letter (MCKMDL00478910).

internet pharmacies from legitimate ones.[33] The December 2007 letter also stated that past communications from DEA "should no longer be taken to mean that DEA approves a specific system." Ex. 18 at 1.

In outlining these new expectations, DEA recognized that distributors historically had reported orders to DEA after shipment.[34] DEA also recognized that its new guidance constituted a significant change and that implementing it would be "harder" and would happen only gradually.[35] Given the informal nature of the new guidance—as well as the complexity of registrants' SOM systems—DEA could not, and did not, set a deadline for distributors' transition from "excessive purchase" systems to systems that included pre-shipping diligence.[36]

H. DEA's Changes Caused Confusion, Affecting Access to Medication.

Plaintiffs assert that "Defendants well understood their obligations under the CSA." Br. at 6. This is yet another disputed fact. DEA's shift in expectations for suspicious order monitoring caused "confusion in the industry."[37] Former DEA employee Kyle Wright testified, "It was truly a -- a different way of looking at it. Everybody was hard and fast on the past. Going past that was a hard reach."[38] DEA's 30(b)(6) witness Prevoznik agreed, "After Mr. Rannazzisi left DEA in 2015, DEA's leadership recognized that it needed to make some important changes to improve how DEA communicated with registrants."[39] In fact, DEA has a "long history of inconsistent interpretations and guidance."[40] In 2015, the Government

[33] Wright Tr. 101:11-102:10; Mapes Tr. 215:5-216:9.
[34] Ex. 19, Sept. 11, 2007 Zimmerman, DEA Pharmaceutical Industry Conference: Wholesale Distribution Diversion Control Program (ABDCMDL00037184 at 7192); Wright Tr. 72:4-10.
[35] Wright Tr. 123:2-16; Mapes Tr. 518:10-14.
[36] Wright Tr. 124:2-125:8; Mapes Tr. 518:2-519:3.
[37] Wright Tr. 120:12-22; Ashley Tr. 58:23-59:6.
[38] Wright Tr. 123:10-13.
[39] Prevoznik 30(b)(6) Tr. 465:3-13, 467:20-469:21.
[40] Ex. 20, May 2016 Report of NACDS Meeting with DEA (WAGMDL00502008).

Accountability Office criticized DEA and recommended "additional guidance for distributors regarding their roles and responsibilities for suspicious order monitoring and reporting."[41] Without such guidance, "distributors are setting thresholds on the amount of certain controlled substances that can be ordered by their customers (*i.e.*, pharmacies and practitioners), which can negatively impact pharmacies and ultimately patients' access."[42]

ARGUMENT

Plaintiffs must support their motion with credible evidence that "would entitle [them] to a directed verdict if not controverted at trial." *Celotex Corporation v. Catrett*, 477 U.S. 317, 331 (1986). This burden is "higher in that it must show that the record contains evidence satisfying the burden of persuasion and that the evidence is so powerful that no reasonable jury would be free to disbelieve it." *Arnett v. Myers*, 281 F.3d 552, 561 (6th Cir. 2002). The Court must draw all reasonable inferences in favor of Defendants. *See Matsushita Elec. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Lindsay v. Yates*, 578 F.3d 407, 414 (6th Cir. 2009).

I. Summary Judgment on Defendants' CSA Compliance Will Not Establish Proof of any Element of Plaintiffs' Claims.

Plaintiffs argue that a ruling on Defendants' CSA compliance will "streamline" trial—that it would provide an "example of [the type of] conduct constituting a common law public nuisance," Br. at 24, "a standard of care for the underlying common law duty" on their negligence claims, *id.*, and relief from their obligation to prove RICO predicate acts, *id.* at 24-25. It will not do any of those things. Plaintiffs' arguments misstate the law and ignore the many disputed facts precluding summary judgment. They also expose Plaintiffs' claims as an impermissible attempt to enforce the CSA through state law causes of action. *See id.*

[41] Ex. 21, June 2015 GAO Report to Congressional Requesters.
[42] *See* Ex. 22, June 2016 Statement of Diana C. Maurer (Strait Dep. Ex. at 19).

A. State Law Claims

Plaintiffs suggest that a finding that Defendants violated the CSA would somehow eliminate the need to prove elements of nearly all of their state statutory and common law claims, but that is not true. Plaintiffs' suggestion is also contrary to their assertion that they "do not seek to enforce Defendants' statutory and regulatory duties" and that "Defendants' liability arises from their failure to use reasonable care under the circumstances, not their failure to abide by federal or state statutes." Dkt. 654 at 74-75.

1. Insufficient Proof of Any Element

For example, Plaintiffs are wrong that their motion could establish a violation of law sufficient to prove an element of statutory public nuisance. *See* OHIO REV. CODE § 4729.35.[43] The CSA does not create a "duty" to maintain effective controls against diversion whose violation could trigger liability under Section 4729.35; the CSA merely provides that diversion control be considered by DEA as one of several factors for issuing, suspending, or revoking registrations. *See* Defs. CSA "Duties" Br., Part II.A-II.B; 21 U.S.C. §§ 823(a)(1), (b)(1).

Plaintiffs fare no better with common law absolute public nuisance. Although conduct proscribed by statute ***may*** be a basis for concluding that an interference with a public right is "unreasonable" for purposes of common law nuisance, it is not "conclusive." RESTATEMENT (SECOND) OF TORTS § 821B, cmt. e (1965) ("Restatement"); *see also Cincinnati v. Beretta Corp.*, 768 N.E.2d 1135, 1142 (Ohio 2002) (looking to Section 821(B) and its comments for guidance

[43] Section 4729.35 declares a nuisance the violation of (1) "laws of Ohio," (2) "laws of … the United States," and (3) board of pharmacy "rule[s]"—not any federal rules or regulations. In any event, Plaintiffs misconstrue the "duties" imposed on registrants under the CSA's regulations. *See* Defs. CSA "Duties" Br., Part II.B.

on the law of public nuisance).[44] Instead, the Restatement suggests that the "unreasonableness" analysis depends on the nature of the statute in question.

Where a statute specifically "declar[es] certain conduct or conditions to be public nuisances . . . [,] there may be no need for a court finding of unreasonableness." RESTATEMENT § 821B, cmt. c. But where the statute is more general and the alleged violation more technical, a finding of a statutory violation does not conclusively prove ***any*** element of a common law absolute public nuisance. *See id.*, cmt. e. Here, the CSA (1) makes no declaration of public nuisance and (2) discusses "controls against diversion" only as one consideration among several for issuing, suspending, or revoking registrations, *see* Defs. CSA "Duties" Br., Part II.A-II.B. Under these circumstances, Defendants' so-called CSA "violations," even if proven, would not establish the element of unreasonableness as a matter of law.

Nor would a CSA violation establish any element of negligence. As the Court has already ruled, Plaintiffs cannot rely on the doctrine of negligence *per se* to impose liability under the CSA. Dkt. 1680 at 24; Dkt. 1861-1.

2. No Private Right of Action

Moreover, any effort to enforce the CSA through common law tort claims is preempted.[45] And, as explained below, Plaintiffs are prohibited from privately enforcing the CSA indirectly through state law causes of action.

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[44] Unlike alleged statutory violations, mere *regulatory* violations cannot form the basis for liability for an absolute nuisance under Ohio law. *See Szuch v. FirstEnergy Nuclear Operating Co.*, 60 N.E.3d 494, 509 (Ohio Ct. App. 2016) (holding that "regulations are not … 'safety statutes'" required to establish absolute nuisance liability); *see also Ogle v. Kelly*, 629 N.E.2d 495, 499 (Ohio Ct. App. 1993) (absolute nuisance claims based on legal violations subject to same standard as negligence *per se* claims); *Kemp v. Medtronic, Inc.*, No, 99-3720, 2001 WL 91119, at *1 (6th Cir. Jan. 26, 2001) (per curiam) ("[U]nder Ohio law, the violation of administrative rules and regulations 'does not constitute negligence *per se*.'") (quoting *Chambers v. St. Mary's Sch.*, 697 N.E.2d 198, 203 (Ohio 1998)).

[45] *See* Dkt. 1926-1, 1883-1, 1873-1, 491-1 at 35-38; *see also Loreto v. Procter & Gamble Co.*, 515 Fed. App'x 576, 578 (6th Cir. 2013) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with its substantive provisions.") (quotation omitted); *id.* at 579 ("The statute's public enforcement mechanism is thwarted if savvy plaintiffs can label as arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA.").

There is no dispute that the CSA does not contain an express private right of action provision and therefore may not be ***directly*** enforced in a private lawsuit. *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). The Supreme Court also has instructed that a state law cause of action may not be used to ***indirectly*** enforce a federal statute where Congress has not authorized private enforcement. *See, e.g.*, *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 118 (2011) (holding that a private party could not indirectly enforce § 340B of the Public Health Services Act, 42 U.S.C. § 256b, through a state law breach of contract claim); *City of Rancho Palos Verdes v. Abrams*, 544 U.S. 113, 119-20 (2005). In *Astra*, for instance, the Supreme Court recognized that the plaintiff's contract claim was "in essence a suit to enforce the statute itself," 563 U.S. at 118, and explained that "[t]hough labeled differently, suits to enforce § 340B and suits to enforce [pharmaceutical pricing contracts] are in substance one and the same. Their treatment, therefore, must be the same, no matter the clothing in which [the plaintiffs] dress their claims." *Id.* at 114 (quotation omitted).

That principle applies here. Congress did not intend for the CSA to be privately enforced. Just as "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities," *id.* at 117, here Congress enacted a comprehensive statutory and regulatory scheme and vested authority with DEA and DOJ to enforce the CSA, *see* 21 U.S.C. §§ 821, 823, 824.[46] Allowing indirect private enforcement of the CSA through state law tort claims would frustrate Congress' intent and contravene its judgments about how the CSA should be enforced. *Astra*, 563 U.S. at 120 ("Far from assisting" the administrative agency, private suits "would undermine the agency's efforts to

[46] *See, e.g.*, *Durr v. Strickland*, 602 F.3d 788, 789 (6th Cir. 2010) (affirming dismissal of declaratory judgment action lawsuit filed by Ohio inmate facing execution arguing that state's "means of execution violate[d] the Federal Controlled Substances Act …, the Federal Food, Drug and Cosmetic Act … and various federal regulations associated with these Acts … because no private cause of action exists under either act").

administer" the statute, because they "could spawn a multitude of dispersed and uncoordinated lawsuits[.]"); *id.* at 118 ("The absence of a private right to enforce the statutory … obligations would be rendered meaningless if [plaintiffs] could overcome that obstacle by suing to enforce the contract's … obligations instead.").[47]

B. RICO Claims

Plaintiffs assert that Defendants violated 21 U.S.C. §§ 841 and 843, which they claim constitute RICO predicate acts, *i.e.*, "the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance," 18 U.S.C. § 1961(1)(D). Br. at 21. On that basis, they ask the Court to rule as a matter of law that they have established both the "pattern" and "racketeering activity" elements of their RICO claim. *Id.* at 23. Even assuming Plaintiffs prove that certain Defendants failed to maintain adequate controls against diversion or to inform DEA of suspicious orders, they are still not entitled to judgment on any portion of their RICO claims for three separate reasons.[48]

1. Defendants' Alleged Violations of Sections 841 and 843 Do Not Constitute Predicate Acts Under RICO.

Section 841. Section 841 makes it unlawful to "distribute[] or dispense" controlled substances "[e]xcept as authorized by [Subchapter I of the CSA]." 21 U.S.C. § 841(a). Plaintiffs do not dispute that Defendants were all registered to distribute opioid medicines pursuant to the CSA's registration requirements. Nor do they claim that Defendants ever distributed opioids to

[47] And this holds true even if private lawsuits might encourage compliance with a federal statute. *Alexander*, 532 U.S. at 286-87 (in the absence of congressional authorization, courts may not authorize private enforcement "no matter how desirable that might be as a policy matter, or how compatible with the statute"); *Astra*, 563 U.S. at 121 (despite evidence of insufficient enforcement resources, declining to infringe on Congress' policymaking function and noting that "Congress did not respond to the reports of inadequate … enforcement by inviting [health centers] to launch lawsuits in district courts across the country.").

[48] Plaintiffs do not assert RICO claims against the Pharmacy Defendants (CVS, Discount Drug Mart, HBC/Giant Eagle, Rite Aid, Walgreens, and Walmart) or certain Distributor Defendants (Anda, H. D. Smith, Henry Schein, and Prescription Supply).

unregistered entities outside the closed system of distribution. Instead, Plaintiffs argue that Defendants failed to maintain "effective controls against diversion," and on that basis assert that their distributions of opioid medicines were "felonious under § 841." Br. at 22.

Plaintiffs' argument is contrary to the plain language of the CSA. The CSA expressly authorizes registrants like Defendants to distribute controlled substances to other registrants within the closed system of distribution. 21 U.S.C. § 822(b). While those distributions must be made "in conformity with the other provisions of [Subchapter I]," *id.*, Plaintiffs identify no provision *of Subchapter I* that Defendants allegedly violated.[49]

Nor can Plaintiffs salvage their claim by reference to Defendants' purported ***regulatory*** violations. *See* Br. at 21 (asserting "that manufacture or distribution in violation of regulations may constitute a violation of § 841"). RICO predicate acts of racketeering consist of violations of enumerated ***felony*** criminal statutes—not administrative rules governing registration. *See, e.g.*, *United States v. Alghazouli*, 517 F.3d 1179, 1184 (9th Cir. 2008) ("[T]he Supreme Court [has] made clear … that a criminal conviction for violating a regulation is permissible only if a statute explicitly provides that violation of that regulation is a crime."); *see also Brown v. First Tenn. Bank Nat'l Ass'n*, 753 F. Supp. 2d 1249, 1260 (N.D. Ga. 2009) (rejecting attempt to use a "civil RICO claim to enforce regulatory provisions"). Indeed, Defendants are not aware of any case holding that a regulatory violation, standing alone, can form the basis of a "felonious" RICO predicate act.[50]

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[49] Subchapter I does *not* require registrants to maintain effective controls against diversion. Instead, the sole reference in Subchapter I to maintenance of "effective controls against diversion" appears in 21 U.S.C. § 823(a)(1). And that provision requires DEA (on delegation from the Attorney General) to consider an applicant's "maintenance of effective controls against diversion" in the course of determining whether to register the applicant; it does not impose any requirements whatsoever on registrants—let alone duties enforceable under the penal code.

[50] None of the cases cited by Plaintiffs is to the contrary. *See United States v. DeBoer*, 966 F.2d 1066, 1068-69 (6th Cir. 1992) (addressing void-for-vagueness argument as to § 841 and noting that underlying regulatory provisions merely provide clarity about conduct that falls outside scope of pharmacist's profession); *United States v. Vamos*,

Section 843. Plaintiffs fare no better with the suggestion that violations of 21 U.S.C. § 843 constitute predicate acts under RICO. Section 843(a)(4) makes it unlawful for a registrant "to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II." Plaintiffs argue that Defendants' alleged failures to inform DEA of suspicious orders violated Section 843(a)(4), and that those failures constitute "racketeering activity" under RICO. Br. at 22. That argument is doubly wrong.

First, Defendants' alleged failure to inform DEA of suspicious orders did not violate any requirement imposed by Subchapter I or Subchapter II of the CSA. While the CSA requires registrants to furnish various records and reports to DEA, *see* 21 U.S.C. § 827 ("Records and reports of registrants"), it did *not* (at any time prior to October 2018) require registrants to inform DEA of "suspicious orders."[51] Indeed, the CSA did not even use the term "suspicious orders" until October 2018. Because suspicious order reports were not required to be "made, kept or filed" under the CSA, any failure to inform DEA of such orders plainly did not violate Section 843(a)(4); *see Cal. Architectural Bldg. Prod., Inc. v. Franciscan Ceramics, Inc.*, 818 F.2d 1466, 1472 (9th Cir. 1987) ("Absent … an explicit statutory duty, failure to disclose cannot be the basis of a fraudulent scheme [under RICO]."). While a ***regulation*** under the CSA previously referenced "suspicious orders," *see* 21 C.F.R. § 1301.74(b), that regulation (1) does not impose

797 F.2d 1146, 1152 (2d Cir. 1986) (addressing challenge to jury instruction and making only passing reference to regulatory scheme in the context of "a brief review of governing principles"); *United States v. Hayes*, 595 F.2d 258, 259 (5th Cir. 1979) (addressing vagueness challenge and consulting regulatory scheme to provide clarity about conduct that violates the actual criminal statute).

[51] This reality is underscored by the fact that Congress, for the first time in October 2018, amended the CSA to require registrants to notify DEA "upon discovering a suspicious order." *See* Pub. L. No. 115-271, 132 Stat. 3894, 3956 (Oct. 24, 2018) (codified at 21 U.S.C. § 832). Had the statute already contained requirements relating to suspicious order reporting, Congress would not have needed to amend the statute in 2018. *See Ross v. Blake*, 136 S. Ct. 1850, 1858 (2016) ("When Congress amends legislation, courts must 'presume it intends [the change] to have real and substantial effect.'"); *see also Pierce Cty., Wash. v. Guillen*, 537 U.S. 129, 145 (2003) (rejecting interpretation of statute that would have rendered the amendment an "exercise in futility").

any "duties" on registrants, *see* Defs. CSA Duties Br. II.B, and (2) even if it did, any purported "violation" would not constitute a felony criminal offense, *see supra* at 15.

Second, violations of Section 843(a)(4) do not constitute RICO predicate acts. RICO's enumerated predicate acts include the "felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance." 18 U.S.C. § 1961(1)(D). But violations of Section 843(a)(4) do not fall within that language because they consist only of "furnish[ing]" false information in, or "omit[ting]" material information from, certain "report[s]" or "record[s]"—not "buying, selling, or otherwise dealing" in controlled substances. 21 U.S.C. § 843(a)(4). While Plaintiffs assert that furnishing false information or omitting material information in reports to DEA "may constitute concealment," Br. at 22, the felonious "concealment" that is actionable under Section 1961(1)(D) has to do with the controlled substances themselves, not recordkeeping.

2. Plaintiffs Have Not Alleged Knowing Violations of the CSA.

Plaintiffs' assertion that Defendants' alleged CSA violations constitute criminal violations of Sections 841 and 843 also fail for another reason: Plaintiffs do not even attempt to satisfy the *mens rea* requirements of those provisions.

Both sections prohibit only "*knowing*[] *or intentional*[]" violations. 21 U.S.C. §§ 841(a), 843(a) (emphasis added). Underscoring this point, a separate provision of the CSA makes it unlawful to "negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under" the CSA. *Id.* § 842 (a)(5). But a violation of that provision is a civil violation, not criminal offense and certainly not a felony. *Id.* § 842(c). Accordingly, it is not sufficient for Plaintiffs to demonstrate, for instance, that a Defendant failed to make a record or report required under the CSA; they must demonstrate by undisputed evidence the Defendant ***knowingly*** submitted a false or

fraudulent record or report. Because Plaintiffs do not even attempt to make this required showing, they are not entitled to partial summary judgment.

3. Plaintiffs Have Not Identified Specific Predicate Acts and Tied Those Acts to Their Alleged Injury.

Plaintiffs' attempt to establish a pattern of racketeering activity in the abstract is inconsistent with their burden of proof under RICO. Because Plaintiffs do not even attempt to identify specific predicate acts by each Defendant, their motion fails.

RICO does not allow private plaintiffs to recover based merely upon the commission of predicate acts by defendants. Rather, in order to recover, a plaintiff must identify the specific predicate acts that a defendant committed, and prove that those predicate acts were a "direct" cause of the plaintiff's injury. *E.g.*, *Hemi Grp. v. City of New York*, 559 U.S. 1, 9 (2010) ("[T]o state a claim under civil RICO, the plaintiff is required to show that a RICO predicate offense … was the proximate cause" of the plaintiff's injury.).

Here, Plaintiffs make no effort to identify the specific predicate acts committed by each Defendant that form the basis for their claims. Instead, they ask the Court to relieve them of the obligation of proving predicate acts at trial based upon abstract allegations of purported violations.[52] That is not how RICO works. It is not enough for Plaintiffs to prove, on the one hand, that Defendants committed predicate acts and also to prove, on the other hand, that Plaintiffs suffered injury. Rather, Plaintiffs must identify the specific predicate acts that allegedly caused them harm. *Kerrigan v. ViSalus, Inc.*, 112 F. Supp. 3d 580, 608 (E.D. Mich. 2015) (rejecting proposition that "Plaintiffs can state their § 1962(c) claims without linking

[52] For example, even if Plaintiffs are right that the failure to inform DEA of a suspicious order placed by a pharmacy in Hawaii is a RICO predicate act (they are not), proof that a Defendant failed to inform DEA of two such orders would not satisfy Plaintiffs' obligation to prove two or more predicate acts unless Plaintiffs could connect those failures to their supposed injury in the Plaintiff counties.

their injuries to a specific predicate act"); *see also Worldspan Marine Inc. v. Comerica Bank*, No. 18-21924-CIV, 2019 WL 2267262, at *4 (S.D. Fla. Feb. 22, 2019) (requiring plaintiff to "identify what acts by a specific Defendant amount to a predicate act that targeted or injured a particular Plaintiff"). Their failure to do so here is fatal.

II. Defendants' Have Presented Substantial Evidence of Their CSA Compliance, Which Precludes Summary Judgment for Plaintiffs.

As described above, DEA's sub-regulatory guidance changed substantially over the relevant time period. In response, each Defendant took steps to update their systems and policies over time—not because they had a "duty" to do so under the CSA and its implementing regulations (which DEA did not change in any material respect), but in order to be responsive to their regulator and because of their shared commitment to keeping controlled substances out of the hands of criminals. At a minimum, there are significant disputed questions of material fact regarding each Defendant's compliance with evolving DEA guidance concerning the identification, reporting, and shipping of suspicious orders that preclude summary judgment.

A. Cardinal Health

1. Every "Fact" Regarding Cardinal Health's Purported Failure to Comply With CSA Duties Is a Disputed Fact.

Plaintiffs' motion previews their opening statement; it does not identify facts that are undisputed. The supposedly undisputed facts are all disputed, as outlined below:

1. **Pre-2008 System for Reporting Suspicious Orders**. The record contains facts and opinion that place in dispute the claim that "[p]rior to 2008, Cardinal Health did not have a system in place to timely report suspicious orders or prevent suspicious orders from being shipped to customers in CT1 jurisdictions." Br. at 76.

- From the 1990s through at least 2007, Cardinal Health ("CAH") had a suspicious order reporting system with two components, Ex. 23 (Cardinal Health DEA Compliance Manual)

at 3940: CAH (1) submitted monthly Ingredient Limit Reports (ILRs, also known as Excessive Purchase Reports) to DEA, and (2) through its distribution center employees, submitted "Excessive Order" reports to DEA. Dkt. 1792-231 at 14-21 (Expert Report of Brian H. Reise). CAH had written policies and procedures describing this system. Ex. 23; Ex. 24 (Standard Operating Procedures, Corporate Quality and Regulatory Compliance). The ILRs identified orders that exceeded a predetermined monthly limit for that pharmacy; the Excessive Order reports identified orders that reflected unusual patterns/frequency/size of ordering, based on the first-hand knowledge of those patterns by the distribution center employees who filled them. CAH contacted the local DEA office before shipping Excessive Orders. Ex. 23 at 3940.

- CAH's system followed a model suspicious order monitoring system developed by National Wholesale Druggists Association ("NWDA") and DEA, which provided for after-the-fact reporting (i.e., reporting the "suspicious" order after it had shipped) and real-time monitoring of "single suspicious orders." The model was detailed in a document titled, "NWDA Suspicious Order Monitoring System." Dkt. 1783-4. DEA called it "an excellent framework for distributor registrants to 'design and operate a system to disclose to the registrant suspicious orders of controlled substances,'" and said that "as proposed, [the model] will meet the reporting requirements of 21 C.F.R. § 1301.74(b)," and has since confirmed that it did so. *Id.* at 11. DEA approved a number of similarly designed systems in the 1980s and 1990s. Dkt. 1792-231 (Reise) at 15. CAH's initial suspicious order monitoring system was consistent with the DEA-approved NWDA system. *Id.* at 16.

- DEA accepted ILRs and Excessive Order reports as compliant with CAH's reporting duties for approximately 30 years and recognized ILRs as the industry standard for reporting suspicious orders. DEA officials who briefed Distributors regarding their CSA

responsibilities testified that the submission of ILRs was standard practice; that DEA was so aware; and that DEA accepted the practice as compliant.[53] DEA never asked or instructed CAH to report differently. Dkt. 1970-4/1983-22 at 515:3-5.

- DEA evaluated CAH's reporting system as part of its regular audits of the distribution centers and did not fault it.[54] The audits reviewed whether CAH was "operating a system that can detect a suspicious order." Dkt. 1983-9 at 129:21-131:23. If not, DEA would "tell the registrant what that registrant was doing wrong," Mapes Tr. 50:23-51:7, or "tell them, you need to add something." Dkt. 1983-9 at 129:21-131:23; 290:8-20. There is no evidence that DEA did so for CAH's Wheeling, WV Distribution Center, which distributed 94% of the opioid medications that CAH supplied to pharmacies in Cuyahoga and Summit, or for the other centers that supplied *de minimis* amounts.

- On December 27, 2007, DEA issued a guidance letter stating, for the first time, that submitting ILRs would not satisfy the suspicious order reporting requirement and revoking any "implicit or explicit" approval of any prior reporting system. Ex. 26. Multiple DEA officials have testified that this "was a change" in DEA's interpretation of the law. *See, e.g.*, Mapes Tr. 125:3-22. One described this as a "significant change" that "was truly … a different way of looking at" suspicious order monitoring. Dkt. 1985:24 at 108:16-110:19, 123:2-14. Another testified in 2011 "that the DEA was aware that it was standard practice in the industry to file suspicious order reports while continuing to ship products ***and that practice had been approved***

[53] Mapes Tr. 92:9-12 (Michael Mapes, former Chief of DEA's Regulatory Section: "From the time I started with DEA in 1977 until we had meetings with the individual wholesalers, *that was … the standard practice*, to submit those [excessive purchase reports); 92:23-25 ("Yeah, *I viewed those [excessive purchase reports] as compliant* with the regulation for suspicious orders."); *see also* Dkt. 1985-24 at 74:8-75:9, 115:17-116:12; Ex. 25 at 548:16-550:3.
[54] Dkt. 1983-22 at 508:2-509:8, 511:8-12; Dkt. 1792-231 at 11.

by the DEA." *United States v. $463,497.72*, 853 F. Supp. 2d 675, 682 (E.D. Mich. 2012) (emphasis added).

- The facts cited above dispute the assertion that CAH was "knowingly shipping orders it had identified as suspicious … until 2008." Br. at 77. DEA markedly changed its guidance to distributors in September 2007 when it adopted a "no ship" requirement and endorsed ABDC's revamped, threshold-based, no-ship reporting system at a conference for distributors. DEA recognized that distributors could not implement new systems immediately. Dkt. 1985-24 at 123:17-25. Three months later, DEA provided this new guidance to all distributors in its December 2007 letter. CAH acted promptly to revise its system to comply with the new guidance and did not "knowingly" violate it. Ex. 27 at 6, 16.

- The audit by Cegedim Dendrite commissioned by CAH did not determine that the company was non-compliant, Br. at 72, because the audit did not consider whether CAH's pre-2008 system complied with ***then-existing*** DEA expectations, but evaluated whether "Phase I" of CAH's system enhancements would comply with DEA's new guidance to industry, as set forth in DEA's December 27, 2007 letter. Dkt. 1792-219 at 964 (evaluating what "an SOM system must be able to analyze" with reference to "DEA's correspondence of December 27, 2007," not prior guidance). Dendrite performed its audit while CAH's upgrades were still in progress and noted that "Phase II" of the enhancements "will address a number of these issues." *Id.* at 960.

- CAH's regulatory expert, a former DEA Diversion Group Supervisor, disputes in detail Plaintiffs' assertion that "Cardinal Health did not have a system in place [before 2008] to timely report suspicious orders or prevent suspicious orders from being shipped to customers in CT1 jurisdictions." He opines that "the system used by Cardinal through 2007 … was reasonable

and consistent with the parameters recommended and approved by DEA …, as well as prevailing industry standards of the time." Dkt. 1792-231 (Reise) at 21.

2. **Pre-2008 Protocol for Internet Pharmacies**. The record contains facts and opinion that place in dispute the claim that, in the pre-2008 period, CAH did not have a specific protocol to monitor internet pharmacy and wholesaler accounts. Br. at 71. Plaintiffs cite a 2005 comment by one employee, but:

- CAH enhanced its processes for identifying internet pharmacies—including creating a new internet pharmacy policy that established practices regarding customer approval, oversight, reporting, and investigations, Ex. 28—after DEA provided guidance in a face-to-face August 2005 meeting. *See id.*; Dkt. 1983-22 at 517:17-21. CAH established thresholds based on the numbers DEA provided. Dkt. 1792-231 (Reise) at 23. CAH trained senior management and staff regarding internet pharmacies, Ex. 29 at 144, and appointed an employee (Brantley) to conduct due diligence inspections of suspected internet pharmacies, including on-site visits. Dkt. 1983-22 at 518:1-6; Ex. 25 at 535:17-536:1, 536:16-537:3. Internal documents reflect that QRA followed the new policies and practices. *E.g.*, Ex. 30 ("If their volume is legitimate, that would be great, but per Eric's comments this needs to be verified."). Pursuant to these policies, the QRA Director recommended the termination of certain internet pharmacies, Mapes Tr. 522:20-523:5; CAH followed his recommendations, *id.* 523:6-9; and CAH notified DEA of the terminations. *See, e.g.*, Ex. 31.

- CAH's former Director of Quality and Regulatory Affairs (QRA), testified that the employee whose comment Plaintiffs cite (who did not work in, or have responsibility for, the QRA section) was wrong. CAH understood that its policies were consistent with DEA's guidance to distributors because the company's point of contact at DEA told CAH in 2007 "we're doing the

right things, and we're going in the right directions, and that we had … a good program" and did not tell CAH that its anti-diversion program "was deficient in any way." Ex. 25 at 548:16-550:3; Ex. 29 at 142.

- Plaintiffs' assertion that CAH lacked a protocol to monitor internet pharmacies is irrelevant, as Plaintiffs have not alleged or presented evidence that internet pharmacies operated in Cuyahoga or Summit, or contributed to the opioid problem there. On the contrary, Plaintiffs contend, and have presented expert evidence, that prescriptions skyrocketed, not because rogue doctors generated prescriptions filled by internet pharmacies, but because legitimate doctors wrote prescriptions according to the prevailing, more permissive standard of care allegedly created by deceptive marketing. *See, e.g.*, Dkt. 513 ¶¶ 9, 174-176, 352-464.

3. **Pre-2008 Staffing**. The record contains facts and opinion that place in dispute the claim that CAH was apathetic about compliance and was "underfunded" and "understaffed" in the pre-2008 period. Br. at 69-70.

- Regarding staffing pre-2007, QRA's Director testified, "I believe I requested two head count and ultimately got two head count." The head count at headquarters was in addition to the "people in the distribution centers" that had "responsibility for reviewing ingredient limit reports and then working in the cage and the vault." Dkt. 1983-22 at 465:1-466:1. QRA's Director from 2007 through 2010 testified that "everything I needed I had, and I had that commitment from the CEO," and he had "adequate resources", and that there was never a time when he asked for additional resources and was denied them. Dkt. 1978-5 at 361:6-11.

- The level of staffing was at all times appropriate to the level of scrutiny called for by DEA's guidance. During the more than 30 years that DEA approved the submission of ILRs,

CAH had sufficient staffing; when DEA provided new guidance in 2007, CAH increased its QRA staffing. Ex. 32.

- Contrary to Plaintiffs' assertion, it is not relevant evidence of "lack of resources for regulatory compliance" that DEA served immediate suspension orders on four CAH distribution centers in 2007-2008. Br. at 70-71. The four centers did not distribute to Cuyahoga or Summit, and CAH's settlement agreement with DEA did not admit that its controls against diversion were inadequate at any distribution center.

4. **CSA Compliance 2008-2012**. The record contains facts and opinion that place in dispute the claim that CAH failed to comply with its CSA duties from 2008 to 2012.

- CAH's regulatory expert disputes that CAH failed to comply. Dkt. 1792-231 (Reise) at 26-39.

- Contrary to Plaintiffs' assertion, it is not relevant evidence of non-compliance that CAH only began to implement an ***electronic*** reporting system in 2007-2008 (the CSA does not require one) and that for some period of time it continued to submit hard-copy reports (DEA accepted them without complaint). When DEA issued its new guidance in 2007, it "recognize[d] that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion," and CAH reasonably understood that DEA's statement applied to it. Dkt. 1792-231 (Reise) at 26.

- It is also not relevant evidence of non-compliance that Deloitte sought to extend its consulting relationship with CAH beyond 2012—it was obviously in Deloitte's self-interest to do so—ostensibly because CAH had not implemented "many" of Deloitte's suggestions and pushed back some of Deloitte's deadlines. Br. at 73.

- CAH's regulatory expert disputes that the company should have reported more suspicious orders than it did, Br. at 73 ("a few dozen suspicious orders per year from 2008 to 2013"), because CAH's reporting during that period was "entirely reasonable and consistent with Cardinal's duties under the CFR." Dkt. 1792-231 (Reise) at 34. In 2007, DEA advised distributors that reporting of "excessive" orders (by ILRs) produced ***too many*** reports and that the agency only wanted to be informed of "truly suspicious" orders. Ex. 33 ("DEA also does not want to receive suspicious order reports that merely reflect volumes that went over a threshold; they wanted reports that are 'true' suspicious orders."); Ex. 34 ("scrub for truly suspicious"). The figures specific to orders from Cuyahoga and Summit "corroborate that Cardinal was appropriately exercising judgment in accordance with its procedures" for identifying and reporting suspicious orders. Dkt. 1792-231 (Reise) at 31.

- CAH's 2012 settlement agreement with DEA itself contradicts Plaintiffs' claim that the company "admitted that it failed to comply with the 2008 MOA and had not engaged in proper due diligence …." Br. at 75. The Agreement states that "[t]he facts alleged in the Order to Show Cause … constitute grounds under which DEA could revoke the DEA registration of Cardinal ***Lakeland*** [distribution center]"—i.e., one center in one state (Florida). CAH admitted only that its due diligence efforts "for some pharmacy customers" and its compliance with the 2008 MOA "in some respects" were inadequate. The 2012 Agreement does not relate to any distribution center that shipped to pharmacies in CT1. As a matter of law, the 2008 and 2012 settlement agreements are not competent evidence on summary judgment, both as settlements and because allegations made by non-parties in separate matters—for which there was never any adjudication on the merits—are not admissible under Rules 401, 402, 403 and 408.

- Activities at the Swedesboro, New Jersey distribution center are not relevant, Br. at 73, because (i) that center does not supply pharmacies in Cuyahoga and Summit and (ii) DEA alleged, but never proved, that the center failed to report or block shipment of suspicious orders.

- The initial thresholds established by CAH in early 2008 were not inflated, as Plaintiffs assert. Br. at 73. DEA evaluated CAH's reporting system as part of its regular audits of the distribution centers and did not fault the initial thresholds. DEA itself raised the production quotas for opioids 39-fold from 1995 to 2010, reflecting a determination that there was an increased legitimate medical need for the medications.

- CAH's regulatory expert opines that thresholds adopted in good faith, based on a distributor's knowledge of its customers and their purchasing patterns (as CAH's thresholds were) are compliant. Dkt. 1792-231 (Reise) at 33.

- Plaintiffs' assertion is also inconsistent with their contention that opioid prescriptions increased because legitimate doctors wrote prescriptions according to the prevailing, more permissive standard of care allegedly created by deceptive marketing. According to Plaintiffs and their experts, the thresholds "based on the previous twelve months' worth of ordering data" would not have been "inflated" in contemporary eyes, Br. at 73, because they reflected the appropriate treatment of chronic pain, based on prevailing treatment guidelines.

5. **Monitoring Chain Pharmacies**. The record contains facts and opinion that place in dispute the claim that CAH gave "preferential treatment to chain pharmacies." Br. at 73.

- Plaintiffs' expert's report calls this assertion into question, for he opined (twice) that CAH provided "almost preferential treatment," while acknowledging "there was clearly some due diligence being conducted." Dkt. 1899-19 at 52-53.

- CAH had different procedures for chain and independent retail pharmacies—not preferential for either—because each presents different issues.[55] For example, CAH contacts the chain pharmacy's corporate office to gather store-level data for due diligence, not the individual store, which is appropriate. Dkt. 1792-231 (Reise) at 31. CAH had a "better picture" of ordering by chain pharmacies "because they're not buying from four or five wholesalers like independents are … [s]o we actually have more scrutiny of the chains than we do independents." Dkt. 1959-14/1975-14 at 347:6-348:15. CAH assigned thresholds to all customers, Ex. 27; flagged suspicious orders by all customers for QRA review, Ex. 36; and reported suspicious orders for chain and independent pharmacies alike. Ex. 37.

- ABDC's post-2007 system—presented at a September 2007 DEA/industry conference as an exemplar—exempted chain pharmacies from the usual requirement that due diligence be conducted for each new pharmacy customer. Ex. 33 at 351.

6. The record contains facts and opinion that place in dispute the claim CAH's system was inadequate because from 2012 to 2015 "Cardinal failed to report more than 14,000 suspicious orders to the DEA, … [including] at least four orders from customers in CT1 jurisdictions." Br. at 77.

- Plaintiffs ignore two critical facts: (1) CAH did not ship any of the unreported orders; and (2) CAH promptly notified DEA in 2018 of the 14,000 unreported orders and the IT error that caused the non-reporting,[56] DEA has yet to ask CAH to submit the reports belatedly or

[55] Ex. 35; *see also* Ex. 27 (explaining that (i) a chain store pharmacist does not share directly in the pharmacy's profits and thus does not have the same financial incentives as a retail independent pharmacist to fill more prescriptions and (ii) chain pharmacies can reasonably be assumed to have greater safeguards in place to monitor and prevent potential diversion).

[56] Ex. 38. Plaintiffs' assertion about the 14,000 orders is further contested in that CAH did report almost all orders that exceeded thresholds set by "base codes." The vast majority of the 14,000 orders that were inadvertently not reported did not exceed the base-code thresholds, but a different set of thresholds based on "sub-base codes," which are an added layer of scrutiny not required by any DEA regulations, but which CAH chose to employ nevertheless.

to fault CAH formally or informally, given that the orders were not shipped and were not reported as a result of an IT error.

- Of the 14,000 orders, pharmacies in Cuyahoga or Summit placed only four (not "at least" four, Br. at 77). None of the four orders shipped, so no county resident had a prescription filled from one of the four orders. Not shipping, as Plaintiffs' regulatory expert has testified, "would obviously keep it from being distributed and it would not lead to diversion." Dkt. 1983-17 at 370:12-24, 371:14-17; 371:18-23. From 2012 to 2018, CAH did report (and blocked shipment of) 119 pharmacy orders from CT1, and more than 200,000 orders nationwide.

In sum, disputed questions of material fact preclude the Court from ruling as a matter of law that CAH's suspicious order reporting during this time-period was inadequate. Plaintiffs presented no evidence that any inadequacy constituted a ***knowing*** violation of the CSA; indeed it is undisputed that CAH reported to DEA, through the ARCOS database, ***all*** orders for opioid medications.

B. McKesson Corporation

McKesson at all times operated a controlled substance monitoring program that met or exceeded its obligations under the CSA and DEA's evolving expectations for distributors. At a minimum, genuine disputes of material fact preclude summary judgment on this issue.

1. McKesson's Pre-April 2008 Suspicious Order Monitoring Program

Prior to April 2008, McKesson monitored the purchases of controlled substances through a process identified in Section 55 of its Drug Operations Manual. *See* Ex. 40, Drug Ops. Manual (MCKMDL00651873). Section 55's policies included a dual reporting structure, with both daily and monthly reports (called "DU-45" reports) immediately reviewed and transmitted to the

(The evidence shows that CAH discovered the issue, not during a 2015 audit, but in the course of a 2018 document collection for the Multistate AG group, Ex. 39 at 807, as CAH advised the Special Master.)

relevant DEA field office by a McKesson Distribution Center Manager or an authorized designee. *Id.* at -1919-21; *see also* Aquino Rpt. ¶ 83 (Dkt. 1939-1/1936-1). The DU-45 reports were submitted to DEA pursuant to 21 C.F.R. § 1301.74(b), and were accepted as such by DEA.[57] The reports identified all orders that exceeded three times the monthly average for a Schedule II or III controlled substance. Ex. 40 at -1919-21, -2180-82. The use of a multiplier to identify suspicious orders was accepted by DEA as an appropriate mechanism for informing DEA about suspicious orders during the time-period that McKesson submitted DU-45 reports.[58] Section 55 also provided additional methods to identify suspicious orders, including requiring employees to review controlled substances orders "before filling" and requiring order fillers "to report to management any unusual purchase request before orders are filled." Ex. 40 at -1923; *see also* Aquino Rpt. ¶ 85.

In response to DEA concerns expressed during the Distributor Initiative, McKesson implemented a Lifestyle Drug Monitoring Program ("LDMP") in May 2007 that focused on the sale of four "lifestyle drugs"—including oxycodone and hydrocodone—identified by DEA. *See* Ex. 41, LDMP Manual (MCKMDL00355251); *see also* Aquino Rpt. ¶¶ 127, 167. Under the LDMP, McKesson augmented its existing Section 55 policies—including the submission of DU-45 reports to DEA—with additional monitoring. Boggs Tr. 102:3-105:2 (Dkt. 1959-4/1975-5); Aquino Rpt. ¶ 174. For the four drugs identified by DEA, orders exceeding a threshold triggered additional diligence by McKesson employees. *See* Ex. 41 at -5252-55. Both

[57] Multiple DEA witnesses confirm that these reports—which the DEA sometimes referred to as "excessive purchase reports"—satisfied 21 C.F.R. § 1301.74(b). Wright Tr. 72:4-10, 72:12-16, 75:2-9; Mapes Tr. 93:21-94:3, 96:9-97:24, 520:14-521:18; Ashley Tr. 30:14-31:4; Aquino Rpt. ¶¶ 88-89, 96-97.

[58] *See supra*, Background Part F; Ex. 12 at -2230, -2247; *see also* Aquino Rpt. ¶¶ 100-114; Br. at 12 (noting that the DEA "backed away from the standard of three times the monthly overage order" *in 2008*).

the Section 55 policies and the LDMP conformed with then-prevailing industry standards and DEA guidance. Aquino Rpt. ¶¶ 98-99, 174.[59]

Plaintiffs' principal criticism of McKesson's pre-April 2008 systems is that McKesson did not "block" suspicious orders. Br. at 79-80. But the record evidence shows that DEA did not require or expect distributors not to ship suspicious orders (as that term is defined in the CSA's implementing regulations) during this time period.[60] Neither the CSA nor the regulations require registrants not to ship such orders. Moreover, DEA knew that McKesson—like all other registrants—was not routinely blocking orders that met the regulatory definition of "suspicious orders," and approved this practice as part of its periodic audit process prior to 2008. Hilliard Tr. 175:12-176:4 (Dkt. 1963-1/1978-12); Aquino Rpt. ¶¶ 96-97. DEA likewise approved of ABDC's suspicious ordering monitoring system—a system materially similar to McKesson's—despite the fact ABDC's pre-2008 system similarly did not block suspicious orders at that time.[61]

Plaintiffs' criticism that McKesson's pre-2008 systems did not identify and inform DEA about "true suspicious orders" is likewise misplaced. Br. at 79. The CSA's implementing regulations (to this day) define a suspicious order as an order of "unusual size, … pattern, … [or]

[59] Plaintiffs point to a document purportedly identifying shortcomings in the LDMP diligence process, but on its face that document indicates that initial diligence had already been completed on the identified stores and "Level 2" diligence reviews were ongoing where appropriate. *See* Pl. Ex. 247. Plaintiffs also cite to an internal LDMP audit conducted two months after the program's launch, which notes the need to ensure that all generic products are captured by the LDMP's unit limit and that customer ordering from multiple distribution centers is accounted for. *See* Pl. Ex. 248. If anything, this document demonstrates McKesson's commitment to improving the effectiveness of the new program that it was in the process of implementing.

[60] Wright Tr. at 72:4-10; Prevoznik 30(b)(6) Tr. at 121:15-19; Mapes Tr. 535:7-536:3; *see also* Aquino Rpt. ¶¶ 94-97. DEA first communicated to McKesson and other distributors its expectation that they not ship "suspicious orders" in late 2007. Ex. 26; Aquino Rpt. ¶¶ 136-140, 154-155. In response to this guidance, McKesson promptly developed and implemented a new system that was consistent with DEA's expectations. *See infra* Part II.B.2.

[61] Mapes Tr. 93:9-20, 187:1-188:13; Aquino Rpt. ¶¶ 108-114. While DEA did not expect distributors not to ship orders meeting the regulatory definition of the term "suspicious orders" prior to 2008, it did expect distributors not to ship orders where the distributor had good reason to believe that the order was destined for the illicit market. *See* Aquino Rpt. ¶¶ 142, 146-148. Plaintiffs' motion does not identify any orders that McKesson shipped to pharmacies to Summit County or Cuyahoga County where McKesson had such knowledge.

frequency." 21 C.F.R. § 1301.74(b). DEA witnesses have testified that McKesson's DU-45 reports were accepted by DEA as fulfilling McKesson's obligation to report suspicious orders. *See supra* n.57. While it is undisputed that many orders meeting the regulatory definition of "suspicious orders" are not truly suspicious in the colloquial sense of the term—*i.e.*, are not likely to be diverted to illicit use—DEA's expectation prior to 2008 was that distributors would "follow what the regs say about unusual size, unusual patterns, or frequency" when identifying and informing DEA about suspicious orders.[62] Accordingly, the testimony of Gary Hilliard (cited at Br. at 79) that McKesson's pre-2008 system was focused on reporting "excessive orders" (rather than the much more limited subset of orders truly at risk of diversion) does nothing to establish that McKesson's systems failed to conform with the requirements of the CSA or DEA's expectations as described in its pre-2008 guidance.[63]

2. McKesson's April 2008 Controlled Substance Monitoring Program

The record evidence shows that McKesson's Controlled Substance Monitoring Program ("CSMP"), which launched in April 2008, also fully satisfied McKesson's obligations under the CSA and DEA's contemporaneous expectations for registrants.

Through the CSMP, McKesson implemented customer-specific thresholds for all controlled substances. Ex. 42, CSMP Manual (MCKMDL00409301 at -9302-04). McKesson set these thresholds by DEA base code, thereby creating a single limit on ordering for all items

[62] Prevoznik 30(b)(6) Tr. 181:3-5; *see also* Mapes Tr. 93:21-94:3 (DEA diversion investigator agreeing that DEA "accepted … excessive purchase reports as compliant with the Controlled Substances Act").
[63] For similar reasons, Plaintiffs' reliance on a *2011* email (Pl. Ex. 240) written by McKesson employee David Gustin to establish the insufficiency of McKesson's pre-*2008* systems is unavailing. Mr. Gustin's personal beliefs regarding the optimal design of a suspicious order monitoring system in light of DEA's 2007 and subsequent guidance cannot alter the fundamental fact that, prior to 2008, DEA accepted "excessive purchase" reports as fulfilling distributors' reporting obligations under the CSA. *See, e.g.*, Mapes Tr. 93:21-94:3; *supra* n.57.

with a shared drug base (e.g., all oxycodone-containing items). *Id.* McKesson's implementation of a threshold-based system was done at the behest of, and with full awareness by, DEA.[64]

Under the CSMP, if a customer placed an order in excess of a threshold, McKesson flagged and did not ship the order. *See* Walker Tr. 381:8-21; *see also* Aquino Rpt. ¶ 179. McKesson also automatically stopped shipment of all further orders for products with the same DEA base code. Ex. 42 at -9306; Aquino Rpt. ¶ 179. In addition to blocking orders that exceeded thresholds, all such orders also triggered an automatic "Level 1" investigation by McKesson to determine why the customer had placed an order in excess of its threshold. *See* Ex. 43 at -9143. If McKesson determined after a "Level 1" review that additional investigation was warranted, McKesson would initiate a more detailed "Level 2" review. *Id.* This review, overseen by a director-level Regulatory Affairs employee, typically involved customer interviews and site visits, among other steps. *Id.* at -9144. Unless the "Level 2" investigation demonstrated the absence of any cause for concern, the order would be reported to DEA as a suspicious order and McKesson would initiate a "Level 3" investigation—in which case sales of *all* controlled substances to the customer would be blocked and the customer could be terminated. *Id.* at -9145; *see* Ex. 42 at -9307-08.[65]

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[64] Walker Tr. 134:15-135:14, 382:9-383:19 (Dkt. 1971-19/1985-11); Ex. 43, March 12, 2014 Presentation to DEA (MCKMDL00409116 at -9133); Aquino Rpt. at ¶ 187. Plaintiffs incorrectly suggest that initial customer thresholds were set too high. McKesson's process for setting thresholds required review of a new customer's past twelve months of sales data in order to determine an customer-specific threshold based on past purchasing patterns. *See, e.g.*, Ex. 43 at -9139-40. McKesson further created a series of default thresholds based size of a customer's business, which would be used absent purchasing history that justified a different threshold. *See id.* The record makes clear that McKesson consistently endeavored "to establish thresholds at a -- at a low number to ensure that all the pharmacies were being evaluated appropriately." Walker Tr. 397:21-398:8, 400:20-22.

[65] Plaintiffs' assertion that there is no evidence of Level 2 or 3 reviews occurring for pharmacies within Summit and Cuyahoga Counties before January 1, 2014, is contrary to the evidence. The record reflects that McKesson undertook Level 2 investigations of numerous pharmacies in Ohio, including in Summit and Cuyahoga Counties. *See, e.g.*, Ex. 44, Sept. 20, 2013 email (MCKMDL00596140) (site visit and review for Cuyahoga County pharmacy); Pl. Ex. 247 (Level 2 review in Warren, OH). In addition, McKesson identified and reported to DEA numerous customers—including several Ohio pharmacies—that it determined after review to pose a substantial risk of diversion. *E.g.*, Ex. 45, Feb. 23, 2012 email (MCKMDL00707092 at -7094) (reporting to DEA); Ex. 46, Feb. 11,

Belying Plaintiffs' assertion that McKesson conducted only "rudimentary" diligence on its customers, *see* Br. at 83, the CSMP also required a thorough process for customer "onboarding." Before agreeing to service a new customer, McKesson required the customer to complete a detailed questionnaire, conducted a site visit, and confirmed that the pharmacy had active state and federal licenses. Ex. 42 at -9308-10; *see also* Ex. 48, Pharmacy Questionnaire (MCKMDL00494348); Aquino Rpt. ¶¶ 184-185. McKesson also conducted substantial due diligence on its existing customers, including requiring customers to sign declarations regarding controlled substance ordering and conducting additional site visits, internet searches, and detailed background investigations by corporate security. Ex. 42 at -9313; Aquino Rpt. ¶ 185. McKesson's CSMP fully complied with the CSA and was consistent with DEA's contemporaneous guidance. Aquino Rpt. ¶ 187.

According to Plaintiffs, the fact that McKesson reassured customers that they would be able to continue with "business as usual" under the CSMP is evidence that the program was flawed. Br. at 83-84. That is nonsense. Plaintiffs' own experts have opined that the diversion of opioids to illicit use by rogue pharmacies and pill mill doctors—*i.e.*, the sort of illicit activity that the CSMP was designed to detect—was only a very minor contributor to the opioid crisis.[66] The overwhelming majority of pharmacies are not bad actors—they fill legitimate prescriptions written in good faith by doctors based upon the prevailing standard of care.[67] Accordingly, there was nothing remotely untoward about the statement to McKesson's pharmacy customers that they would be able to conduct their "business"—*i.e.*, providing patients with the FDA-approved medicines that their doctors prescribed in good faith—"as usual." *See* Hilliard Tr. 267:1-268:21

2009 email (MCKMDL00707025) (same); Ex. 47, CSMP Actions (MCKMDL00533984) (identifying Ohio pharmacies denied distribution of controlled substances and reported to DEA after review).

[66] *See, e.g.*, Keyes Rpt. 18 (Dkt. 2000-9/1999-9).

[67] Distributors' Motion for Summary Judgment on Proximate Causation Grounds (Dkt. 1920-1) at 12-13.

(explaining that McKesson wanted to "enhanc[e] [its] programs" in a way that did not "disrupt customers'" ability to fill legitimate prescriptions of FDA-approved medications).

a. McKesson's Threshold Change Review Process Included Diligence To Ensure That Change Requests Were Appropriate.

Plaintiffs incorrectly point to McKesson's threshold change request process as evidence of the CSMP's inadequacy. Under the CSMP, each McKesson customer was assigned an initial threshold. Over time, those customers could require increases in their assigned thresholds for myriad legitimate reasons (*e.g.*, the only other pharmacy in town closed). Accordingly, the CSMP established procedures that would allow pharmacies to request threshold increases. Ex. 42 at -9305-06. Under those procedures, a threshold would only be changed if—upon review by McKesson's Regulatory Affairs department—it was determined that the customer had shown a legitimate change in circumstances that warranted a threshold increase. *Id.*; Hilliard Tr. 341:19-342:11.

Plaintiffs have not come forward with evidence—let alone undisputed evidence—that McKesson systematically failed to obtain sufficient justification prior to increasing thresholds. Their brief does not, for instance, purport to identify even a single pharmacy in Cuyahoga or Summit Counties that inappropriately received a threshold increase after inadequate due diligence.

Nor do the stray internal emails cited by Plaintiffs establish by undisputed evidence the insufficiency of McKesson's procedures. Plaintiffs point to a July 2012 email purportedly establishing that McKesson was "too liberally granting threshold increases." Br. at 85. But in fact the email shows the opposite, as it demonstrates McKesson's commitment (1) to appropriate training of employees regarding threshold increase procedures and (2) to ensuring that all threshold increase requests be adequately documented with specifics. *See* Pl. Ex. 261 ("As for a

specific reason for the increase in usage. Business growth should be accompanied by specific examples of what is generating that growth …. Many of you do this very well.").[68]

Plaintiffs' criticism of McKesson for providing customers with threshold warning reports is likewise misplaced. McKesson provided these reports to ensure that the supply of FDA-approved medications to patients presenting legitimate prescriptions was not inappropriately restricted. *See* Cavacini Tr. 95:15-96:15 (Dkt. 1959-19/1975-19). McKesson, however, did not encourage customers to seek threshold increases. Mahoney Tr. 261:9-15, 272:15-273:12 (Dkt. 1966-12/1981-6) (threshold change request must be "customer generated"). And a customer who received a threshold warning report was subject to exactly the same battery of diligence that applied to all threshold increase requests.[69]

Finally, Plaintiffs assert that McKesson failed adequately to investigate threshold increase requests from "national account customers" (*i.e.*, national retail pharmacies). That is not the case. McKesson developed the CSMP against the backdrop of the Distributor Initiative, in which DEA specifically focused on small, independent pharmacies.[70] DEA confirmed their limited focus on independent pharmacies at the 2007 distributor conference, during which the DEA had ABDC present its DEA-approved SOMs program that expressly "exempted" retail chain pharmacies from the requirements of "'[k]now [y]our [c]ustomer' [d]ue [d]iligence." Ex.

[68] The handful of other emails cited by Plaintiffs are similarly unavailing. For example, the fact that a single McKesson employee was feeling "overwhelmed" by his responsibilities, *see* Pl. Ex. 262, does nothing to establish that McKesson inappropriately granted threshold increases or otherwise failed to conduct adequate due diligence.
[69] *See* Hilliard Tr. 276:7-277:11; Ex. 49, Jan. 19, 2011 email (MCKMDL00518329). No evidence supports Plaintiffs' assertion that McKesson "recognized the impropriety" of the threshold warning process. McKesson phased out this process in 2013 as part of the general evolution of its CSMP program and use of advanced data analytics to set thresholds. Ex. 50, Nov. 2013 Talking Points (MCKMDL00639211).
[70] *See* Ex. 51, March 2007 Rannazzisi Presentation (US-DEA-00002413 at p. 50) (PowerPoint created by Joseph Rannazzisi noting that the DEA identified "rogue pharmac[ies]" and included "[n]o [c]hain [p]harmacies" in the list); *see also* Ex. 52, May 8, 2007 email (MCKMDL00535364) ("DEA does not view Natl Chains as the issue").

19 at -7190. In accordance with this contemporaneous guidance, McKesson originally focused its 2008 CSMP programs primarily on independent and smaller chain pharmacies.

Nonetheless, McKesson did not disregard or fail to conduct diligence for larger national chains. Rather, as early as May 2007 McKesson implemented a process of working directly with the internal corporate regulatory teams at various national chains in order to monitor controlled substance orders.[71] While different from the approach taken for independent pharmacies—which lack the robust internal regulatory teams present at national chains—this system nonetheless effectively monitored retail national chains in line with DEA guidance.

b. McKesson Stopped Submitting DU-45 Reports at DEA's Request.

Plaintiffs' criticism of McKesson for allegedly not informing DEA of suspicious order during the time-period from January 2009 until July 2013 is likewise misplaced.[72]

In 2008, McKesson worked in close coordination with DEA to establish a system that would allow McKesson to disclose suspicious orders to DEA headquarters. As part of this process, DEA expressly agreed that

> McKesson will no longer be required to provide suspicious order reports or any other type of reports regarding excessive purchase of controlled substances to the DEA Field Offices and that this Agreement shall supersede any DEA regulatory requirements to report suspicious orders to DEA.

See Pl. Ex. 249 at ¶ II(1)(c). In designing the agreed-upon system, moreover, DEA officials expressly instructed McKesson that "*[a] suspicious order should be reported to DEA only after*

[71] *See* Ex. 52 (stating that McKesson will "go to the headquarters of the respective customer and obtain confirmation that their pharmacies are dispensing these drugs based on prescriptions they receive"); Ex. 53, Aug. 28, 2008 email (MCKMDL00543758) (discussing Level I investigations of chain stores); Ex. 42 at -9306.

[72] Although Plaintiffs state that McKesson stopped submitting reports in May 2008, the uncontradicted record evidence is that McKesson continued to submit DU-45 reports until January 2009. *E.g.*, Walker Tr. 383:20-384:2 ("Q. … When did McKesson cease providing DU45 reports to the DEA? A. I think in January of '09, we finally reached mutual agreement that we had a system that could talk back and forth. And I think in January of 2009 is when we ceased providing DU45s.").

your company has completed its due diligence and determined that you will not complete the sale because it is suspicious." Ex. 54, Nov. 4, 2008 email (MCKMDL00536051 at -6052) (emphasis added). In other words, DEA instructed McKesson to inform it about only the orders for which, after due diligence, McKesson determined with a "high degree of confidence" that there was a risk of diversion. Walker Tr. at 391:3-17. McKesson complied with DEA's request and, in January 2009, stopped submitting excessive purchase reports in favor of the new, agreed-upon system.[73]

Against this backdrop, Plaintiffs' criticism of McKesson's procedures for informing DEA of suspicious orders from January 2009 to July 2013 is misplaced.[74] At a minimum, disputed questions of material fact preclude the Court from ruling as a matter of law that McKesson *knowingly* violated any provision of the CSA (or its implementing regulations). *See* 21 U.S.C. § 841, 843 (establishing penalties for "knowing[] or intentional[]" violations). The overwhelming weight of the record evidence indicates that McKesson did not inform DEA about all orders of unusual size, pattern or frequency because it believed in good faith that DEA only wanted to be informed about the subset of those orders that McKesson, upon investigation, determined to be at a substantial risk of diversion. Walker Tr. 390:1-394:10; *see also supra* n.65.

Plaintiffs are also wrong to suggest that McKesson's non-reporting of certain orders constituted a failure to maintain adequate controls against diversion. *First*, at all times since

[73] Walker Tr. at 382:9-383:19; Aquino Rpt. ¶ 186; Ex. 43 at -9133; Ex. 55, Jan. 22, 2009 email (MCKMDL00355691) ("[DEA] received paper suspicious transaction reports (DU45) from St. Louis and Birmingham and are questioning why we are still sending paper reports.").

[74] The parties agree that McKesson reinstituted the practice of reporting all suspicious orders effective August 1, 2013, shortly after receiving revised guidance from DEA. Rafalski Rpt. 72-73 & n.269 (Dkt. 2000-22/1999-21); *see* Br. at 87. Plaintiffs have not come forward with *any evidence whatsoever* of any alleged "reporting" violations on the part of McKesson post-dating July 31, 2013, and thus are plainly not entitled to summary judgment for the period after that date. Moreover, as described in Defendants' Combined Brief of Distributors and Manufacturers in Support of Partial Summary Judgment on Statement of Limitations Grounds (Dkt. 1896-1), Plaintiffs' negligence, nuisance and RICO claims are time-barred insofar as they relate to pre-October 2013 conduct. Accordingly, Plaintiffs have not identified any reporting failures relevant to their timely RICO, negligence or nuisance claims.

January 2009, McKesson blocked—*i.e.*, did not ship—*all* orders of controlled substances that exceeded the thresholds established under the CSMP. Boggs Tr. 72:3-73:9. As Plaintiffs' expert James Rafalski acknowledged, whether reported or not, blocked orders "remain[] safely" at the distributors' warehouse and do not "have the potential to be diverted." Rafalski Tr. 368:6-13. Because McKesson blocked all such orders of controlled substances, its purported "reporting" failures could not have contributed to diversion. *Id.* at 370:15-371:23.

Second, McKesson continued to identify and inform DEA about all (in Plaintiffs' parlance) "true suspicious orders," *i.e.*, orders that McKesson determined were at risk of diversion. In other words, McKesson (at DEA's request) investigated orders of unusual size, pattern or frequency, and reported to DEA only the orders it determined were truly suspicious, in the colloquial sense of the term.[75] This practice, if anything, enhanced controls against diversion by allowing DEA to focus its law enforcement efforts on those pharmacies most in need of greater scrutiny.

Third, it is undisputed that McKesson reported *all* prescription opioid orders it shipped to DEA through the ARCOS database. McCann Rpt. ¶¶ 47, 71 (Dkt. 2000-14/1999-13). As DEA has acknowledged, information submitted to the ARCOS database provided DEA with a complete picture of all opioid distributions during the relevant time-period, including sufficient information to identify any suspicious order patterns.[76] McKesson's reporting to ARCOS of all controlled substance distribution of opioids defeats any claim that McKesson knowingly concealed any suspicious orders from DEA.[77]

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[75] As DEA admits, orders that meet the regulatory definition of "suspicious" may well be "false positives" that do not pose a risk of diversion. Wright Tr. 208:5-24; *see* Prevoznik 30(b)(6) Tr. 307:18-308:2 ("Q. [If] an order that is unusually large, does that order necessarily lead to diversion? A. [I]t may or it may not.").

[76] *See* Distributors' Motion for Summary Judgment on Plaintiffs' RICO and OCPA Claims (Dkt. 1921-1) at 13-14.

[77] *See, e.g., U.S. ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) ("prior

Finally, Plaintiffs have not identified any diversion in Ohio connected to McKesson. That failure is fatal to its summary judgment motion.

3. McKesson's Settlement Agreements

Plaintiffs' brief repeatedly cites two DOJ settlement agreements with McKesson, as well as letters written by DEA in connection with those matters. *See, e.g.*, Pl. Ex. 255. However, *allegations* made by non-parties in separate matters—for which there was never any adjudication on the merits—are not competent evidence on summary judgment.[78] Accordingly, Plaintiffs' references to unsubstantiated allegations by DEA and DOJ must be disregarded.

McKesson's narrow "acceptance of responsibility" in its 2017 settlement agreement does not alter this result. The provision cited by Plaintiffs merely acknowledges that McKesson, at some unidentified time after January 1, 2009, "did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the [Dear Registrant] Letters." Br. at 78. Plaintiffs' assertion that this "acknowledgement" entitles them to summary judgment is wrong for three reasons.

First, McKesson did *not* admit to violating either the CSA or its implementing regulations. Rather, the agreement states only that McKesson failed to report orders that should have been detected "based on the guidance contained in" the Dear Registrant Letters. Those

government knowledge … can negate the scienter required" to establish a fraud on the government); *United States v. Pendergraft*, 297 F.3d 1198, 1209 (11th Cir. 2002) (holding that where the senders knew that the recipient of information would not be misled, "'they could not have had an intent to deceive' as required to establish scienter"); *see also Universal Health Servs., Inc. v. United States ex rel Escobar*, 136 S. Ct. 1989, 2003-04 (2016) (similar).

[78] *Hobart Corp. v. Dayton Power & Light Co.*, No. 13-cv-115, 2017 WL 5956911, at *21 (S.D. Ohio No. 29, 2017) (holding that making "the content of prior settlement agreements available for use in related litigation contravenes the very purpose of Rule 408"); *Beans v. City of Massillon*, 2016 WL 7492503, at *5 (N.D. Ohio Dec. 30, 2016) ("conclusory allegations, speculation, and unsubstantiated assertions are not evidence"); *see also Mass. Mut. Life Ins. Co. v. DLJ Mortg. Capital, Inc.*, 251 F. Supp. 3d 329, 332 (D. Mass. 2017) (concluding that defendant's prior settlement with DOJ and the facts recited therein were not admissible or cognizable on summary judgment).

letters do not have the force of law and do not accurately describe distributors' obligations under the CSA. *See* Defs. CSA "Duties" Br., Part II.D.1.

Second, Plaintiffs invoke 21 U.S.C. §§ 841 and 843 to assert that McKesson's purported reporting violations constitute felonies. By their express terms, however, both provisions criminalize only knowing or intentional conduct. In the 2007 settlement agreement, McKesson did not admit to any knowing or intentional violations of the CSA. Moreover, the evidence shows that McKesson did not inform DEA about certain orders based on a good-faith belief that DEA did not want McKesson to do so. *See supra* Part II.B.2.b.

Third, Plaintiffs must demonstrate not only that McKesson committed RICO predicate acts, but also must demonstrate a "direct relation" between identified predicate acts and their injury. *See supra* Part I.B. Plaintiffs similarly must prove that McKesson's alleged reporting violations were a direct cause of their injury on their common-law claims. *See, e.g.*, *Cleveland v. Ameriquest Mort. Secs., Inc.*, 615 F.3d 496, 503 (6th Cir. 2010). McKesson acknowledged in the 2017 settlement agreement only that it failed to report "certain" orders—not that it failed to report any suspicious orders placed by and delivered to pharmacies in Summit or Cuyahoga. Moreover, McKesson *did not ship* any orders it identified as potentially problematic under the terms of the CSMP during the relevant time-period, and so any reporting violations could not conceivably have caused Plaintiffs any injury. Accordingly, McKesson's non-reporting of unspecified orders—orders that, by definition, did not ship—cannot be used to relieve Plaintiffs of their obligation to identify at trial the wrongful acts that purportedly caused them harm.

C. ABDC

Even if Plaintiffs' interpretation of the CSA and its regulations were correct (and it is not), there are more than enough genuine issues of material fact requiring denial of Plaintiffs' motion. Indeed, there is extensive record evidence that creates disputed issues of fact: DEA

helped develop and expressly approved ABDC's system for identifying and reporting suspicious orders in 1998; DEA requested that ABDC train its diversion investigators in the early 2000s (and lauded ABDC for those efforts); and DEA endorsed ABDC's redesigned system in 2007. Plaintiffs also neglect to inform this Court that their own expert testified that ABDC complied with its obligations. Instead of taking on evidence that does not fit within their skewed version of the facts, Plaintiffs simply make their own value judgments as to how ABDC's system stacked up against their (incorrect) view of the law. But Plaintiffs' value judgments are not evidence. The actual evidence, as detailed below, undermines Plaintiffs' motion.

Pre-2007. Plaintiffs acknowledge that, prior to 2007, ABDC used a threshold-based system to flag suspicious orders exceeding the 3-times average sale benchmark, and instructed its employees to report orders that were of unusual size or frequency, or which deviated from the normal ordering pattern. Br. at 90-92. But Plaintiffs fail to acknowledge that ABDC, from 1998 to 2007, operated a SOM system that DEA helped develop and expressly approved.

Between 1996 and 1998, ABDC's predecessor, Bergen Brunswig,[79] developed a new computer-based SOM system that would compare a customer's controlled substance orders against a standard representing an average of the customer's prior four months of orders.[80] All orders exceeding a specified percentage of the customer's prior 4-month average order history would be reported to DEA daily.[81] This was in addition to monthly excessive purchase reports.[82] Before implementing the system, in 1996, Chris Zimmerman, Bergen Brunswig's Manager of

[79] ABDC was formed in 2001 when AmeriSource Health Corporation and Bergen Brunswig Corporation merged. The newly formed ABDC adopted Bergen Brunswig's 1998 diversion control system. *See* Ex. 56, Email from C. Zimmerman to P. Ross (ABDCMDL00273269-70).
[80] Ex. 57, 9/30/96-7/23/98 correspondence between Bergen Brunswig and DEA (ABDCMDL00315783 at 91-93).
[81] *Id.*
[82] *Id.*

Corporate Security, wrote to Thomas Gitchel, DEA's Chief of the Liaison and Policy Section, which was responsible for interpreting DEA's regulations,[83] "to introduce the [DEA] to an innovative new system under development by [Bergen Brunswig] to monitor and report customer orders of controlled substances which fit the suspicious order criteria outlined in 21 C.F.R. § 1301.74(b)."[84] Zimmerman's letter led to a collaboration between Bergen Brunswig and DEA to develop the new system.[85]

DEA weighed in on the type of report Bergen Brunswig proposed to provide,[86] and agreed to test Bergen Brunswig's new system at three distribution centers.[87] With DEA's approval, those three distribution centers began submitting daily faxes to DEA's Los Angeles field office,[88] which responded positively to this new system.[89] On July 23, 1998, DEA's then-Chief of the Liaison and Policy Section, Patricia Goode, issued a letter with the subject "approve suspicious order monitoring system" to Bergen Brunswig:

> This is to ***grant approval*** of your request to implement on a nationwide basis your newly developed system to identify and report suspicious orders for controlled substances and regulated chemicals, ***as required by Federal regulation***. DEA managers who have been involved with the testing of the system have relayed their ***positive opinions*** regarding its ability to provide information in a fashion which is not only useful overall, but is also responsive to the needs of individual DEA offices.[90]

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[83] Prevoznik 30(b)(6) Tr. 5/17/19 1119:9-24.
[84] Ex. 57, 9/30/96-7/23/98 correspondence between Bergen Brunswig and DEA (ABDCMDL00315783 at 91-93); Gitchel was the highest-ranking official at DEA responsible for interpreting the SOM regulations.
[85] *Id.* (ABDCMDL00315783 at 83-94); *see also* Ex. 58 (US-DEA-00025671).
[86] *Id.* (ABDCMDL00315783 at 89-90).
[87] *Id.* (ABDCMDL00315783 at 88).
[88] *Id.*
[89] *Id.* (ABDCMDL00315783 at 86-87).
[90] *Id.* (ABDCMDL00315783) (emphasis added); Ex. 58. The regulation referred to in the approval letter is 21 C.F.R. § 1301.74(b), which states: "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

Zimmerman testified that, between 1998 and 2007, "the orders were reported after they were shipped" in step with "the program that we developed in conjunction with DEA over a two-year process."[91] Thomas Prevoznik, DEA Section Chief of Pharmaceutical Investigations and corporate representative, acknowledged that the 1998 letter approved ABDC's SOM system, which was designed to report suspicious orders ***after*** they already had been shipped.[92] Former DEA Investigator Michael Mapes testified that he separately approved ABDC's controlled substance monitoring program between 2001 and 2003.[93]

From 1998 to 2007, ABDC continued to work with various DEA field offices by tailoring information to the specific requests of the office,[94] and assisting with DEA investigations.[95] DEA also asked ABDC to continue to ship to customers DEA was investigating.[96] In addition, ABDC helped train DEA's diversion investigators.[97] In October 2004, DEA gave ABDC an award in recognition of its contribution to drug enforcement and to DEA's training program.[98]

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[91] Zimmerman 30(b)(6) Tr. 213:24-214:14 (Dkt. 1972-16/1985-28).
[92] Prevoznik 30(b)(6) Tr. 5/17/19 at 1139:10-16 (Dkt. 1969-14/1983-1) ("Q: … Mr. Prevoznik, the DEA approved for implementation nationwide a suspicious order monitoring system that reported orders to the DEA on a daily basis after the report – after the order had already been shipped, correct? A. Yes.").
[93] Mapes Tr. 102:4-106:13.
[94] For example, the Dallas distribution center changed the threshold limit from 3 times the normal monthly ordering pattern of a customer to 6 times based on telephone conversation with DEA's Dallas field office, Ex. 59 (ABDCMDL00401601); and the Orlando distribution center began running queries to submit additional reporting to DEA at the request of a DEA field office, Ex. 60 (ABDCMDL00315974). Attached are examples of daily suspicious order reports sent to DEA field office by various ABDC distribution centers. See Ex. 61 (ABDCMDL00316041).
[95] Ex. 62, 5/25/07 letter from ABDC to DEA Administrator, Karen Tandy (ABDCMDL00398309 at 10-13); Ex. 63, AmerisourceBergen's History of Cooperation with DEA, as attachment to 6/7/07 letter from ABDC to Sen. Diane Feinstein (ABDCMDL00398338 at 40-45).
[96] Ex. 64, Contact Form Comments (ABDCMDL00398235); Ex. 65, Suspicious Order Investigation Summary, 10/6/05-3/12/07 (ABDCMDL00301218).
[97] Ex. 66, 10/25/04 letter from ABDC CSRA to ABDC Distribution Center Managers and Compliance Coordinators (ABDCMDL00315829); Ex. 67, 1/12/05 letter from DEA Special Agent in Charge, John McCarty, to Bergen Brunswig Manager of Regulatory Affairs, Steve Mays (ABDCMDL00315862); Ex. 68, 9/25/03 letter involving same (ABDCMDL00315795); Ex. 69, 1/14/04 letter involving same (ABDCMDL00315827).
[98] Ex. 63, AmerisourceBergen's History of Cooperation with DEA, as attachment to letter from ABDC to Sen. Diane Feinstein, dated 6/7/07 (ABDCMDL00398338 at 43).

Prevoznik testified that ABDC was deserving of this recognition.[99] Plaintiffs' expert Rafalski testified that ABDC should be "proud" of its collaboration with DEA.[100]

DEA's express approval of ABDC's SOM system and close relationship with ABDC from 1998 to 2007 shows unequivocally the ABDC maintained the required controls against diversion from 1998 to 2007. At a minimum, for purposes of Plaintiffs' motion, it shows there is at least a genuine dispute of material fact that precludes summary judgment for Plaintiffs.

Post-2007. Plaintiffs assert that "[t]he year 2007 marks a key shift in [ABDC's] suspicious order monitoring policies" because that year DEA initiated an enforcement action against ABDC and suspended the registration of ABDC's Orlando distribution facility, leading to a settlement agreement in which ABDC agreed to alter its order monitoring system. Br. at 92-93. Plaintiffs argue that "[d]espite this 'complete change' to its order monitoring policy in 2007, … [ABDC] continued the practice of shipping some orders it identified as suspicious, with little or no documentation as to whether a due diligence investigation was conducted to show such orders were unlikely to be diverted into illegal channels." *Id.* at 94.

Given Plaintiffs' incomplete recitation of the relevant history, some context is necessary. As noted, DEA's approval of ABDC's program remained in effect from 1998 to 2007, during which time ABDC worked side-by-side with DEA to train the DEA's diversion investigators. In 2006, Rannazzisi took over as the Deputy Assistant of DEA's Office of Diversion Control.[101] On April 19, 2007, DEA issued an Order to Show Cause and Immediate Suspension of

[99] Prevoznik 30(b)(6) Tr. 5/17/19 1146:7-16 ("Do you recall DEA awarded AmerisourceBergen a certificate of appreciation in 2004? … The Witness: Yes. Q. Okay. And they were deserving of that recognition? … The Witness: Yes.").
[100] Rafalski Tr. 228:16-229:2.
[101] Rannazzisi Tr. 391:2-18.

Registration ("ISO") for ABDC's Orlando, FL distribution center,[102] alleging that ABDC failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.[103] The ISO did not focus on the ***shipping*** of suspicious orders; instead, the ISO focused on volume and customer due diligence.[104]

When it received the letter, ABDC already had cut off supplying controlled substances to most of the pharmacies named in the ISO.[105] Between April and June 2007, ABDC and DEA worked hand-in-hand developing a new system to detect and report suspicious orders.[106] Former DEA investigator Mapes testified that it was his "understanding that the [ABDC] system was an example of a system that contained the type of information that we were looking for."[107] On June 22, 2007, ABDC and DEA entered into a Settlement and Release Agreement in which ABDC "agree[d] to maintain a compliance program designed to detect and prevent diversion of controlled substances" and, following DEA reviews of the system, DEA would dissolve the ISO by August 25, 2007.[108] The Agreement did ***not*** include a financial penalty and stated that it was ***not*** "an admission of liability by [ABDC]" and "[ABDC] expressly denies the DEA's allegations."[109] ABDC's new diversion control program had three pillars: (1) new customer due diligence; (2) an order monitoring program that flagged orders of interest and were reviewed by a trained diversion control team member; and (3) ongoing customer due diligence.[110]

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[102] Ex. 70, ISO for Orlando facility (ABDCMDL00269383-87).
[103] *Id.*
[104] *Id.*
[105] Ex. 62, 5/25/07 letter from ABDC to DEA Administrator Karen Tandy (ABDCMDL00398309 at 10-13).
[106] Mays Tr. 246:6-247:15, 254:18-258:9 (Dkt. 1966-15/1981-10).
[107] Mapes Tr. 181:24-182:14.
[108] Ex. 71, 6/22/07 Settlement and Release Agreement between DEA and ABDC (ABDCMDL00279854-61).
[109] *Id.* (ABDCMDL00279854 at 55).
[110] In addition, in 2007, ABDC began submitting daily reports of all controlled substance transactions to DEA. Ex. 72, Program Overview exhibit for ABDC's diversion control programs (ABDCMDL00004603 at 28); Ex. 71, 6/22/07 Settlement and Release Agreement between DEA and ABDC (ABDCMDL00279854). At a Pharmaceutical Industry Conference in Houston, TX on Sept. 11-12, 2007, DEA presented ABDC's 2007 diversion control program to the industry and held this program up to the industry as an exemplar program. *See* Ex. 73, Print out of DEA

First, as one part of ABDC's new customer due diligence program, ABDC launched the Form 590 nationwide for all new retail pharmacy customers as well as customers that had orders flagged by the SOM system. DEA exempted retail chain pharmacies and hospitals from completing the Form 590.[111] The Form 590 questionnaire gave ABDC information on the amount of controlled substances ordered, anticipated ratio of controlled substances purchased vs. total purchases, key prescribing doctors in the area utilizing the pharmacy, and payment practices of the pharmacy's customers.[112]

Second, ABDC implemented a new order monitoring system that grouped customers by their DEA classification: hospital/clinic, retail pharmacy, practitioner, distributor.[113] Within each group, ABDC classified the customer according to its size.[114] ABDC determined the size based on the total dollar value of prescription sales for both controlled and non-controlled substances.[115] With DEA's knowledge,[116] ABDC kept the multiplier of three for ARCOS controlled substances, and for each category of customers, ABDC set a threshold for each class of drug.[117] To determine the threshold, ABDC calculated a yearly average of the order volume

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Office of Diversion website giving the agenda and summary of the Sept 11-12, 2007, Pharmaceutical Industry Conference in Houston, TX (ABDCMDL00046628); DEA – Diversion Control Division, *Pharmaceutical Industry Conference* (Sept. 11, 2007) https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/ 13th_pharm/index.html.

[111] Ex. 72, Program Overview exhibit for ABDC's diversion control programs (ABDCMDL00004603 at 4-8); Zimmerman 30(b)(6) Tr. 213:24-214:14; Ex. 74, Presentation describing ABC's new Diversion Control Program given by Chris Zimmerman at DEA's Sept. 11, 2007 Pharmaceutical Industry Conference (ABDCMDL00269266).

[112] Ex. 75, Program Overview on ABDC diversion control programs (ABDCMDL00004578 at 82); *see also* Ex. 76, ABDC Form 590 Practitioner Questionnaire (ABDCMDL00293362).

[113] *Id.*

[114] *Id.*

[115] *Id.*; Ex. 77, Prescription Drug Diversion Program PowerPoint prepared by Chris Zimmerman, VP & Chief Compliance Officer and Davis May, Sr., Dir. Diversion Control & Federal Investigations prepared for Mar. 4, 2015 Meeting of the Audit & Corporate Responsibility Cmte ("Mar. 4, 2015 PowerPoint") (ABDCMDL00004969 at 76).

[116] Mays Tr. 246:6-247:15.

[117] Ex. 75, Program Overview on ABDC diversion control programs (ABDCMDL00004578 at 82).

and then multiplied it by three.[118] If a customer ordered over this threshold over the course of 30 days, the order would be flagged as an order of interest for review.[119]

If an order was flagged, it was held by ABDC until the order was investigated.[120] A trained reviewer at the Distribution Center initially reviewed the order.[121] The reviewer looked at the customer type, whether the customer had a known, legitimate, and well-established need for high volumes of controlled substances, and the typical ordering patterns for that customer.[122] The reviewer had three options: (1) release the order and ship it; (2) cancel the order; or (3) escalate the order for Corporate Security & Regulatory Affairs ("CSRA") review.[123] "Generally, the OMP reviewers released Orders of Interest for hospitals and the Department of Defense."[124] A reviewer would cancel an order, but not identify it as suspicious, if, "for example, the order quantity was obviously not correct based on prior purchases or the customer reported the order as mistakenly submitted."[125] Orders that required further review—for example, a retail pharmacy exceeding its threshold—were sent to CSRA to make a final determination.[126]

Once an order was identified for review, a CSRA representative for the particular customer's region analyzed if the order was suspicious.[127] The CSRA representative considered the totality of the circumstances surrounding the order, including: "the size of the pharmacy; the ordering practices, purchase history, dollar volume and product mix; the percentage of controlled

[118] *Id.*; *see also* Ex. 77, Mar. 4, 2015 PowerPoint (ABDCMDL00004969 at 76).
[119] *Id.*; *see also* Ex. 77, Mar. 4, 2015 PowerPoint (ABDCMDL00004969 at 77).
[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] *Id.*
[124] Ex. 75 (ABDCMDL00004578 at 83).
[125] Ex. 77.
[126] *Id.*
[127] *Id.*

substance purchases; follow-up interviews with customer employees; rationale for order; and the time of the order within the month."[128] The representative would then: (1) determine that the order was suspicious and report it to DEA; (2) determine that the order was not suspicious, but reject the order; or (3) release the order for shipment.[129] From 2007 through present day, ABDC does not ship orders it reports as suspicious to DEA.[130] Expert Robert Buskey opined that "[b]ased on the documents I reviewed and my experience and training at DEA, ABDC's 2007 order review went well-beyond ABDC's statutory and regulatory requirements" and that "[t]he program utilized many investigative techniques and struck an important balance of identifying suspicious orders while ensuring legitimate orders were shipped."[131]

Third, ABDC's new program included ongoing customer due diligence measures. In 2007, in connection with DEA Orlando ISO, ABDC implemented a "Do Not Ship List." Customers end up on the "Do Not Ship List" based on information learned through ABDC's own investigations or through other sources.[132] Since 2007, ABDC has added almost 800 customers to its "Do Not Ship List" nationwide.[133] ABDC also utilized a Form 590 with existing customers whose orders were flagged by the SOM system.[134] Since 2007, the Form 590 has undergone frequent enhancements to take into account trends and emerging issues.[135]

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[128] *Id.*
[129] *Id.*
[130] *Id.*; *see also* Ex. 72, Program Overview exhibit for diversion control programs (ABDCMDL00004603 at 11-12).
[131] Buskey Rpt. ¶ 139 (Dkt. 1939-4/1936-4).
[132] *See, e.g.*, Ex. 78, ABDC Controlled Substance "Do not Ship" List revised Jan. 4, 2008 (ABDCMDL00360259); Ex. 79, ABDC Controlled Substance "Do not Ship" List revised Jan. 15, 2010 (ABDCMDL00363215); Ex. 80, ABDC Controlled Substance "Do not Ship" List revised Aug. 20, 2013 (ABDCMDL00336962); Ex. 81, ABDC Controlled Substance "Do not Ship" List revised May 28, 2014 (ABDCMDL00337006).
[133] Ex. 82, ABDC Controlled Substance "Do not Ship" List revised Apr. 30, 2018 (ABDCMDL00300218).
[134] Ex. 83, 6/27/07 CSRA PowerPoint presentation on the "AmerisourceBergen Corporation Diversion Control Program effective June 25, 2007" (ABDCMDL00313757); Zimmerman 30(b)(6) Tr. 200:3-21.
[135] *See* Ex. 84, 6/30/07 Form 590 (ABDCMDL00360282); Ex. 85, 8/10/10 Form 590 (ABDCMDL00169950); Ex. 86, 11/15/12 Form 590 (ABDCMDL00364348); Ex. 87, July 2013 Form 590 (ABDCMDL00282315); Ex. 88, August 2013 Form 590 (ABDCMDL00301767); Ex. 89, list of "Talking Points" for ABDC Sales Associates relating to Form 590 (ABDCMDL00302282).

In addition, ABDC retained Michael Mapes as an independent investigator for ABDC's pharmacy customers upon his retirement from DEA in January 2008, and from 2008 through 2013, Mapes conducted audits at ABDC customer sites.[136] During these audits, Mapes reviewed the pharmacy's compliance with controlled substance regulations.[137] Mapes also conducted yearly audits of ABDC's system.[138] Mapes reviewed new customer due diligence files, thresholds for each drug family and customer size, ABDC's Do Not Ship List, several individual customer and drug reports, CSRA 590 forms, an audit checklist, and completed CSRA files for new customers and customers who had an increase in thresholds over the last year.[139] Although Mapes identified areas for minor improvement during a 2013 audit, Mapes concluded that ABDC's system "is well managed and appears to be very effective at mitigating the risk associated with the distribution of controlled substances."[140]

Based on these facts, Buskey opined that "ABDC's Diversion Control Program goes well-beyond the requirements and does not just meet the minimum standard for compliance" and that "ABDC's Diversion Control Programs throughout the years have all far exceeded the statutory and regulatory requirements."[141] Even ***Plaintiffs' expert*** Whitelaw acknowledged that ABDC did what was necessary to meet its obligations.[142]

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[136] *See, e.g.*, Ex. 90, 1/21/14 email from Michael Mapes summarizing a site visit/audit (ABDCMDL00003541).
[137] *See id.*
[138] *See, e.g.*, Ex. 91, 11/8/10 report summarizing Mapes' Nov. 3-5, 2010 audit of the ABC Order Monitoring Program and providing recommendations (ABDCMDL00398877); Ex. 92, 7/27/12 report summarizing July 23-27, 2012 audit of the ABC Order Monitoring Program and providing recommendations (ABDCMDL00398882); Ex. 93, 7/27/14 report summarizing Mapes' June 11-12, 2014 audit of the ABC Order Monitoring program and providing recommendations (ABDCMDL00398896).
[139] *See, e.g.*, Ex. 91, 11/8/10 report summarizing Mapes' Nov. 3-5, 2010 audit of the ABC Order Monitoring Program and providing recommendations (ABDCMDL00398877).
[140] Ex. 93, 7/27/14 report summarizing Mapes' June 11-12, 2014 audit of the ABC Order Monitoring program and providing recommendations (ABDCMDL00398896).
[141] Buskey Rpt. ¶ 206.
[142] Whitelaw Tr. 649-50 (Dkt. 1972-7/1985-19). (A. "ABC was not trying to stand out as a stellar performer. They were just doing the basics that they had to do to get by. … Q. So the minimum to meet the regulations, but nothing more, is that your testimony? A. The minimums to meet your obligations.") (objection omitted).

Plaintiffs argue that "[d]espite this 'complete change' to its order monitoring policy in 2007, … [ABDC] continued the practice of shipping some orders it identified as suspicious, without little or no documentation as to whether a due diligence investigation was conducted to show such orders were unlikely to be diverted into illegal channels." Br. at 94. Plaintiffs, however, present no evidence to meet their summary judgment burden.

Plaintiffs first assert that ABDC reported only a small number of suspicious orders from Summit County for 2010 and 2012. Br. at 94. But the fact that only a small number of orders were reported as suspicious in certain years merely reflects the fact that ABDC was distributing to pharmacies that did not place a substantial number of suspicious orders and/or the fact that ABDC was often able to review orders of interest and determine that they were not suspicious before being required to report the orders to DEA as suspicious.

Plaintiffs also claim that, after 2007, ABDC continued to ship orders it reported to DEA as suspicious. Br. at 94. Plaintiffs point only to two orders over a ten-year period (from 2007-2018) as their "proof" of this point. First, the transactions are much more entangled than it appears from Plaintiffs' description. In fact, it is not even clear that the orders ABDC purportedly shipped are the same orders as those reported as suspicious to DEA. (*See* Pl. Ex. 299; Pl. Ex. 300). And, in any event, Plaintiffs do not present any evidence to tie these particular orders to any injury by any party.

Given that, Plaintiffs are left to argue that ABDC's Form 590 practices (*i.e.*, gathering information from customers) were ineffective, because ABDC did not have Form 590 information for all customers. Br. at 94-95. But DEA did not require that ABDC have Form 590 information for every customer.[143] Notably, DEA exempted retail chain pharmacies and

[143] Zimmerman 30(b)(6) Tr. 213:24-214:14; Ex. 74, Presentation describing ABC's new Diversion Control Program

hospitals from completing the Form 590.[144] In addition, Prevoznik (DEA) testified that "the DEA has not issued any best practices regarding what methodology to use to know your customer to distributors and manufacturers in the controlled substances context."[145] Moreover, it is possible that ABDC previously completed a Form 590 for a customer but that the form had not been maintained in the file or lost.[146] Prevoznik testified that "there was not any sort of requirement by the DEA of the maintenance of due diligence files."[147]

Finally, Plaintiffs assert that Buskey's report "does not dispute any of the facts" in Plaintiffs' motion and that "Mr. Buskey asserts that ABDC's SOM program was adequate based on an interpretation of the CSA—and in particular, of the reporting and no-shipping duties—at odds with the official pronouncements of DEA and with the most recent pronouncements and enactments of Congress." Br. at 95-96. This is false. Buskey's report details important facts about ABDC's SOM system—including the comprehensive nature of the post-2007 program—that contradict Plaintiffs' summary judgment assertions. Buskey's opinion that ABDC exceeded all of its statutory and regulatory duties is based on those important facts.[148]

given by Chris Zimmerman at DEA's Sept. 11, 2007 Pharmaceutical Industry Conference (ABDCMDL00269266).
[144] Ex. 72, Program Overview exhibit for ABDC's diversion control programs (ABDCMDL00004603 at 4-8); Zimmerman 30(b)(6)Tr. 213:24-214:14; Ex. 74, Presentation describing ABC's new Diversion Control Program given by Chris Zimmerman at DEA's Sept. 11, 2007 Pharmaceutical Industry Conference (ABDCMDL00269266).
[145] Prevoznik 30(b)(6) Tr. 216.
[146] Kreutzer Tr. 160:2-160:9 (Dkt. 1963-21/1979-14); Ex. 94, E. Cherveny Email re: CSRA 590 Validation Project (ABDCMDL00140921).
[147] Prevoznik 30(b)(6) Tr. 1212.
[148] Buskey Rpt. ¶ 206.

D. Prescription Supply

Prescription Supply Inc. ("PSI") is a small, family-run wholesale distributor. Located near Toledo,[149] its market share in Cuyahoga and Summit Counties combined is less than 0.7%.[150]

Plaintiffs ask the Court to conclude what no state or federal regulator has found in the company's 64-year history: that PSI failed to "maintain effective controls against diversion of controlled substances."[151] In fact, Ohio regulators found the exact opposite. After more than a year-long review of PSI's compliance, including an on-sight inspection, records review, and management interviews, the Ohio Board of Pharmacy concluded in 2018 that "[a]dequate systems are in place to detect and deter drug diversion,"[152] systems PSI has maintained since at least 2008.[153] The Board also found that an adequate system was "in place to identify and report suspicious orders" of controlled substances.[154] Summary judgment is thus improper on these facts alone.

Yet Plaintiffs ignore this evidence, contending PSI did not protect against diversion in its reporting and shipping duties. Neither contention is true.

To start, Plaintiffs have not established that PSI ever received a suspicious order. Their data analyst, Craig McCann, "flagged" transactions based on algorithms concocted by James

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[149] C. Harbauer Tr. 12:8-13:2 (Dkt. 1962-17/1977-22); T. Schoen Tr. 196:24-197:3 (Dkt. 1970-17/1984-10).
[150] *See* Dkt. 1878-1/1879-1 at 5, Fig. 2.
[151] Dkt. 1924-1 at 96.
[152] Ex. 95, C. Harbauer Decl. ¶ 4; Ex. 96, State of Ohio Board of Pharmacy Wholesaler – Category 3 Non-Pharmacy Inspection Report, June 6, 2018 (PSI-099454-60; 099456); Ex. 97, T. Schoen Dep. Ex. No. 22 (PSI0000007-0000083).
[153] *See* J. Schoen Tr. 33:7-34:18 (Dkt. 1970-16/1984-9).
[154] Ex. 96. Although the Board *suggested* it "may be beneficial" for PSI to keep additional supporting documentation when investigating whether an order was truly suspicious, DEA's own testimony in this case confirms the CSA imposes no such requirement. *See, e.g.*, Wright Tr. 143:2-12 ("Q: And the exercise that the registrant goes through to do some due diligence to really bear out whether the order is, in fact, truly a suspicious order or not, that due diligence exercise, is there a regulatory requirement to document that due diligence? … A: No.").

Rafalski, an ex-DEA investigator.[155] But both men admit they never reviewed whether any "flagged" transaction actually filled a suspicious order.[156] And both only assumed that PSI performed no due diligence.[157]

Their flawed methodology yields flawed results. Nine of the ten allegedly suspicious orders identified by Summit County,[158] for example, were placed by pharmacist Daniel Karant when his pharmacy's primary distributor was simply out of stock.[159] Karant is a member of the Summit County Board of Health.[160] He is a member of the City Council for the City of Norton—another Plaintiff in this MDL.[161] He is past-Chairman of the Ohio Pharmacists Association Emergency Preparedness Task Force.[162] And he is last year's winner of the Bowl of Hygeia: awarded by the Ohio Pharmacists Association to "pharmacists who possess outstanding records of civic leadership in their communities."[163] Plaintiffs' methodology is a dragnet.

Although Plaintiffs fail to identify any suspicious order, much less a suspicious order in Summit or Cuyahoga Counties, they nevertheless accuse PSI of failing to timely report such orders. They suggest that PSI's Suspicious Order *Monitoring* Reports disclosed suspicious orders, but that because those reports were made to DEA at the end of each month, the reports were untimely.

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[155] *See* Dkt. 1903-2/1906-2 at 2-3.
[156] Rafalski Tr. 192:10-21, 366:17-367:2; Rafalski Tr. 489:16-19, 633:2-634:2; McCann Tr. 94:3-7, 149:17-23, 283:11-284:22 (Dkt. 1966-17/1981-12). Of course, Rafalski assumed only generally that Defendants' lack of due-diligence records equated to no due diligence actually being conducted. His report does not even mention PSI.
[157] Rafalski Tr. 167:1-168:25; McCann Tr. 288:10-289:2. Rafalski's misguided assumption that the lack of due-diligence documentation means no due diligence occurred is a general one. Rafalski has never offered an opinion on PSI specifically.
[158] Ex. 98, Pl. Resp. to the Am. and Clarified Disc. Ruling 12 Supp. Interrogs. Issued to Pl., Sec. D and Ex. B at 8.
[159] Ex. 99, Karant Decl. ¶¶ 1, 6-7.
[160] *Id.* ¶ 2.
[161] *Id.* ¶ 2; *see* case no. 1:18-op-45767.
[162] Ex. 99 ¶ 2.
[163] *Id.* ¶ 3.

These reports, however, were designed with the help and blessing of DEA in 1997 and received by DEA for over 15 years without complaint.[164] And while the reports, which contain orders for above-average amounts of product, were generated and sent by PSI to DEA, PSI's Substance Control Manager followed DEA guidance before that occurred by investigating these and other orders that gave him pause.[165] Indeed, PSI has gone so far as to report a suspicious *customer*, which the CSA does not even require.[166] PSI has thus met its reporting duty. At the very least, there is a material-fact issue over whether PSI exercised "[s]ubstantial compliance" with the security requirements, generally, and the reporting requirement, specifically. 21 C.F.R. § 1301.71(b).

As for shipping, both PSI's Rule 30(b)(6) representative and its Controlled Substance Manager testified unequivocally that the company has never shipped a suspicious order.[167] And it is undisputed that PSI held orders with which it was uncomfortable.[168] Indeed, comparing PSI's logs of orders versus logs of sales shows the company blocked a significant amount of orders between 2008 and 2016, scores of which predated 2013.[169]

Plaintiffs argue that because PSI generated Suspicious Order Monitoring Reports after shipment, the company could not have performed due diligence on potentially suspicious orders. But while these end-of-month summaries were generated after-the-fact, the underlying data (customer orders) was received and manually entered into PSI's system by the company's

[164] K. Harbauer Tr. 80:19-83:3 (Dkt. 1962-18/1977-23); Ex. 100, K. Harbauer Dep. Ex. No. 1; Ex. 101, K. Harbauer Dep. Ex. No. 2; Ex. 102, K. Harbauer Dep. Ex. No. 3.
[165] J. Schoen Tr. 120:10-121:9. Moreover, according to DEA, "pharmacies that are around the corner from one another may have vastly different profiles that are acceptable," and DEA "feels very strongly" that these are circumstances "that only a distributor can know." Strait 30(b)(6) Tr. 40:3-41:16 (Dkt. 1971-4/1984-22).
[166] Ex. 95 ¶ 6; Ex. 103, handwritten notes memorializing calls (PSI-0001400).
[167] T. Schoen Tr. 182:15-16; J. Schoen Tr. 122:19-20.
[168] Counsel for Plaintiffs conceded as much at James Schoen's deposition. J. Schoen Tr. 148:15-16 ("I know you've held orders. I get it. And I'm not disputing that."); *see also id.* 146:12-147:8.
[169] Ex. 104, K. Harbauer Decl. ¶¶ 2-3.

Controlled Substance Manager.[170] At the same time, he reviewed customer-sales history to identify orders of interest like those in the Suspicious Order Monitoring Reports, a process PSI automated in 2008.[171] PSI thus had ample opportunity to identify truly suspicious orders—an opportunity of which the company made productive use.[172]

In sum, Plaintiffs have not and cannot meet their high burden of showing "that the record contains evidence satisfying the burden of persuasion and that the evidence is so powerful that no reasonable jury would be free to disbelieve it." *Arnett*, 281 F.3d at 561. Indeed, a reasonable jury could find in seven weeks—as the Ohio Board of Pharmacy did in more than a year—that PSI had "[a]dequate systems … in place to detect and deter drug diversion" and "to identify and report suspicious orders" of controlled substances. The Court should deny Plaintiffs' motion.

E. Walmart

Plaintiffs' distorted account of Walmart's anti-diversion efforts finds no support in the evidence. Plaintiffs have offered no expert testimony whatsoever regarding Walmart's SOM programs, whereas Walmart provided an expert report from a former DEA official who found that "Walmart's suspicious order monitoring system was sufficient and effective to detect and report suspicious orders to DEA." Tongring Rpt. 1 (Dkt. 1939-32/1936-32). Walmart maintained extensive controls against diversion—including extensive controls against theft and loss—of which SOM was just one part. *Id.* at 12-13. And Walmart's SOM program appropriately leveraged its status as a self-distributor: Walmart knew its customer because it was itself. *Id.* at 5. Unsurprisingly, therefore, while DEA repeatedly audited Walmart's distribution centers, DEA never found Walmart's SOM systems deficient in any way. *Id.* at 14-15; *see, e.g.*,

[170] J. Schoen Tr. 34:6-18.
[171] J. Schoen Tr. 33:7-34:18.
[172] Ex. 104 ¶ 3; *see also* T. Schoen Tr. 182:15-16; J. Schoen Tr. 122:19-20.

Dkt. 1866-45, 46. And Walmart's distribution centers also were certified by VAWD throughout the relevant time. *See, e.g.*, Dkt. 1866-47, 53, 55.[173] Plaintiffs offer no basis to second-guess DEA and VAWD. At a minimum, Plaintiffs' allegations are the farthest thing from "undisputed."

1. At All Relevant Times, Walmart's Automated Order Monitoring Systems Effectively Identified Suspicious Orders.

From 2011 until Walmart stopped self-distributing opioids in April 2018, Walmart employed automated SOM systems to flag outlier orders for review. *See* Tongring Rpt. 8-11. These systems are memorialized in written policies, *see* Dkt. 1866-35, 37, 38, in records showing that Walmart personnel reviewed and cleared flagged orders (including orders from Cuyahoga and Summit Counties),[174] and in records showing that SOM reports were filed with DEA.[175]

Plaintiffs compare Walmart's systems to a hypothetical alternative under which every order exceeding the largest order from the preceding 6 months would be deemed suspicious, and claim that Walmart "shipp[ed] numerous suspicious orders" under this rubric. *See* Br. at 100. But Plaintiffs cite no authority for their proposed methodology, and DEA witnesses testified there is no such one-size-fits-all approach to SOM. *See* Prevoznik 30(b)(6) Tr. 179:22-180:15; *see also* Dkt. 1906-2 at 3-4, 11. Instead, DEA witnesses emphasized that each registrant can and should develop a SOM methodology suited to its business, *see* Prevoznik 30(b)(6) Tr. 1177:15-19 (Dkt. 1969-14/1983-11), which, as applied to Walmart, means considering that Walmart distributes only to its own pharmacies, *see* Tongring Rpt. 5-6. Notably, the amount of controlled substances ordered by Walmart pharmacies in the relevant jurisdictions, as a

[173] VAWD is a program operated by the National Association of Boards of Pharmacy to ensure that distribution facilities are operating legitimately, are validly licensed, and are employing best practices. *See* Dkt. 1866-57.
[174] *See, e.g.*, Ex. 105 (WMT_MDL_000043808); Ex. 106 (WMT_MDL_000043807).
[175] *See, e.g.*, Ex. 107 (WMT_MDL_000016090); Ex. 108 (WMT_MDL_000047661); Ex. 109 (WMT_MDL_000005602).

percentage of overall volume, fell well within the range DEA has identified as appropriate, *see* Dkt. 1866-3 at 5-6, and Walmart's share of the total volume of opioids distributed to both counties was an amount that Plaintiffs' own expert characterized as *de minimis*, *see id.* at 3. Cases where courts or DEA have found SOM systems inadequate involve a failure to adhere to the distributor's own established SOM policies, leading to actual widespread diversion from the distributor's supply chain.[176] Plaintiffs fail to identify even a single order they maintain should have been reported *under the actual standards* applied by Walmart, and thus no order that should have been reported and was not. *See* Dkt. 1866-3 at 10.

Plaintiffs' additional scattered criticisms of Walmart's automated SOM systems in no way establish a violation of the CSA, let alone support their common law claims:

- From 2017 until Walmart ceased self-distributing controlled substances in 2018, Walmart implemented an algorithmic order-flagging program developed by an independent industry expert. *See* Tongring Rpt. 10-11; Dkt. 1866-6, 43. Plaintiffs do not even mention this time period in their discussion of Walmart's SOM systems.

- From 2015 to 2017, Walmart used enhanced item- and store-specific thresholds that identified orders based on information particular to specific item/store combinations. *See* Tongring Rpt. 9-10; Dkt. 1866-6. Plaintiffs complain that these thresholds generally would not flag orders below 2,000 dosage units (or 20 100-count bottles) per week. *See* Br. at 103.[177] But the SOM regulation expressly lists size as a relevant criteria, and in any event a 20-bottle order is not large. *See* 21 C.F.R. § 1301.74(b). Plaintiffs present no evidence that a 20-bottle weekly threshold is at all unreasonable for a self-distributing pharmacy chain like Walmart.

- From 2011 to 2015, Walmart's systems flagged orders over 50 bottles, as well as orders that exceeded a 30% rolling four-week average for the store/item combination. *See* Tongring Rpt. 8-9; Dkt. 1866-6, 35. Beginning in 2012, Walmart also flagged for further review all orders for 20 or more bottles of a Schedule II controlled substance. *See* Tongring Rpt. 9. Plaintiffs claim these systems were under-inclusive because larger orders were more likely to be flagged. Br. at 102. But the regulation itself makes both size and frequency relevant criteria, and Walmart's pharmacies

[176] *See, e.g.*, *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 212 (D.C. Cir. 2017); *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 Fed. Reg. 36487, 36503 (Drug Enf't Admin. July 3, 2007).

[177] Plaintiffs' claim is an oversimplification of Walmart's SOM program. While there was generally a 2,000-dosage unit minimum for review, that amount could be and was adjusted lower for a variety of reasons. *See, e.g.*, Hiland 30(b)(6) Tr. 315:17-316:6.

were shipped controlled substances at most once per week before October 2014 and twice per week after that. *See* Hiland 30(b)(6) Tr. 46:6-15, 55:6-10 (Dkt. 1962-30/1978-10).

Plaintiffs' quibbles could be raised with almost *any* threshold-based order flagging system. And such complaints are particularly unpersuasive in the context of Walmart's additional controls against diversion. Throughout this time, *all* orders were subject to manual review by Walmart's distribution center employees. *See* Hiland 30(b)(6) Tr. 169:13-170:16. And, as another means to monitor ordering and prevent diversion, Walmart also audited inventory for discrepancies between amounts ordered and dispensed. *See* Beam Tr. 149:11-150:21 (Dkt. 1956-16/1974-16).

Plaintiffs cite testimony that they characterize as saying Walmart's SOM thresholds were set "for business purposes," Br. at 103, but the cited testimony actually says that Walmart designed its SOM systems to identify orders that "didn't make sense for the business," Hiland 30(b)(6) Tr. 404:3-5. That, of course, is precisely what it means for an order to be suspicious, and what DEA representatives have said a registrant should do. *See* Prevoznik 30(b)(6) Tr. 1177:15-19 (registrant should "review its own business model and design a SOM system that fits its designed method of distribution"). Plaintiffs conduct no analysis—and present no expert testimony—to show that the thresholds employed were inappropriate for Walmart's self-distribution business.

Plaintiffs also claim Walmart's systems were inadequate because Walmart's pharmacies could order through McKesson in addition to through Walmart's self-distribution channels. *See* Br. at 103, 105. But the undisputed facts show that all orders were placed in the first instance with Walmart's distribution center, which would relay orders to McKesson only if Walmart did not carry the product or it was out of stock. M. Johnson Tr. 116:9-117:2, 230:7-12, 241:20-242:8 (Dkt. 1963-8/1978-19). McKesson maintained its own SOM system, and, beginning in 2015, Walmart's review of flagged orders included orders relayed to McKesson. *Id.* 117:18-24,

119:14-121:15. Plaintiffs' insinuation that McKesson provided a route to evade Walmart's SOM system is thus contrary to the record. Indeed, Plaintiffs do not point to a single example in the relevant jurisdictions of a McKesson order placed to evade Walmart's SOM system.

Finally, Plaintiffs highlight testimony that orders were reduced to comply with Walmart's policies limiting order size. *See* Br. at 102. As an initial matter, there is nothing problematic about restricting orders to certain levels, so long as orders are not reduced to evade review. *See* Prevoznik 30(b)(6) Tr. 1055:15-19. Indeed, Plaintiffs' argument is peculiar given that Plaintiffs elsewhere accuse Defendants of "flooding" the market. Orders that Walmart reduced before shipping were *also* investigated and reported if found to be suspicious.[178] Specific to this litigation, there is no evidence that any order placed from a Walmart pharmacy in Summit or Cuyahoga Counties ever exceeded Walmart's internal policy limits or was cut.

Unable to gain traction attacking Walmart's policies, Plaintiffs suggest that (despite all evidence to the contrary) Walmart's employees did not actually follow those policies. Br. at 102. Plaintiffs assert, for example, that there is no evidence of reports being filed with DEA. That is false: The record contains uncontradicted evidence of SOM reports filed by Walmart under all these automated systems, just as it includes monthly reports to DEA before 2011.[179] And while none of the reports filed under the systems in place from 2011-2017 concerned orders placed by pharmacies in Plaintiff Counties, there is no evidence of any actual suspicious order placed by a pharmacy in those counties that should have been reported to the DEA, let alone diversion from Walmart's supply chain there. *See* Dkt. 1866-3 at 10. This is unsurprising, since Walmart only operated between fifteen and seventeen pharmacies in these counties (compared to roughly 4,000 nationwide) during the relevant period, all of which ordered controlled substances at rates well

[178] *See, e.g.*, Ex. 110 (WMT_MDL_000009427-28); Ex. 111 (WMT_MDL_000008089-90).
[179] *See* Ex. 107 (WMT_MDL_000016090); Ex. 108 (WMT_MDL_000047661); Ex. 109 (WMT_MDL_000005602).

within the range DEA has declared appropriate. *Id.* at 3, 5-6. The record also contains documentary evidence showing that orders from pharmacies in Plaintiff Counties were flagged internally and investigated by Walmart's compliance personnel, and there is no suggestion or evidence that these orders were wrongly cleared.[180]

Plaintiffs also cite internal Walmart documents that they claim show Walmart "did not have a complaint [sic] system in place," Br. at 104, but these documents show nothing of the sort. Each proposes improvements to Walmart's SOM systems, but none contains any analysis of the CSA or admission that prior systems were legally inadequate. *See* Pl. Exs. 312, 313, 321, 322.[181] The mere fact that Walmart improved its SOM systems does not mean that its prior systems were insufficient. *See* FED R. EVID. 407 (later measures to avoid harm cannot be introduced as evidence of prior violation); *see also, e.g.*, *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 292 (6th Cir. 2015). Indeed, using SOM improvements to prove a violation would create a perverse incentive never to improve an already-compliant system. If anything, Walmart's improvements to its systems show it was responsive to changes in the pharmaceutical industry. *See* Tongring Rpt. 20.

2. Walmart Also Had a Compliant SOM Program Before 2011.

Plaintiffs' primary attack on Walmart's SOM system centers on the allegation that, "[p]rior to 2011, Walmart had not designed any system to identify suspicious orders." Br. at 99; *see also id.* at 100-01, 104. Because the limitations period for Plaintiffs' state law claims extends back no further than April 2014, this allegation is irrelevant. *See* Dkt. 1872 at 6.

[180] *See* Ex. 105 (WMT_MDL_000043808); Ex. 106 (WMT_MDL_000043807).
[181] To justify the expenditure of funds to make these improvements, these documents identify enhanced regulatory compliance as a benefit of the expenditure. *See, e.g.*, Pl's Ex. 312 (listing "[c]ompliance with Federal law" as a "benefit[ ]"). Listing "compliance" as a justification for a budget request cannot reasonably be construed as an admission that those systems would otherwise violate the law.

Regardless, Plaintiffs' claim is disputed and wrong. Plaintiffs misleadingly cite the deposition of one Walmart employee who testified that Walmart had no *written* policy requiring distribution center employees to monitor for suspicious orders. *See* Br. at 100 (citing Abernathy Tr. 42:23-43:5). But it is irrelevant that Walmart did not memorialize this pre-2011 procedure in writing. *See* Tongring Rpt. 6-7. DEA has made clear that there is no requirement that a SOM policy be written, *see* Prevoznik 30(b)(6) Tr. 358:21-359:1, and Plaintiffs cite no contrary authority. Moreover, the record shows that Walmart's tenured order fulfillment team was trained to monitor for suspicious orders as they were filled and did in fact engage in such review.[182] This type of manual review is consistent with the CSA: DEA's 30(b)(6) representative testified that it "does not matter" whether "a registrant reviews orders manually or uses an automated system." Prevoznik 30(b)(6) Tr. 180:12-15. In addition, Walmart's distribution center generated and reviewed monthly reports identifying any outlier orders of controlled substances, which were then faxed to DEA on a monthly basis. *See* Tongring Rpt. 7-8; Hiland 30(b)(6) Tr. 169:22-170:16, 221:6-10. While Plaintiffs claim there is no evidence of reports filed with DEA in this period, Plaintiffs fail even to mention these monthly reports, and the record contains copies of these reports and confirmations that they were faxed to DEA.[183]

Unable to marshal evidence to support their claims, Plaintiffs rest their critique of Walmart's pre-2011 efforts on their proclaimed disbelief of the undisputed testimony offered by every Walmart witness that Plaintiffs questioned about Walmart's system of manual order review. Br. at 101.[184] As the party bearing the ultimate burden of proof, Plaintiffs cannot just

[182] *See* Tongring Rpt. 6-7; Hiland 30(b)(6) Tr. 45:10-46:24, 52:8-13, 169:17-170:16, 219:10-220:8; Hiland Tr. 85:22-87:8, 88:24-90:6 (Dkt. 1962-31/1978-11); Sullins Tr. 45:16-24, 51:6-55:9, 59:23-60:12 (Dkt. 1971-7/1984-25); Abernathy Tr. 41:9-43:5 (Dkt. 1956-1/1974-1).
[183] *See, e.g.*, Ex. 112 (WMT_MDL_000044441-99); Ex. 113 (WMT_MDL_000046008-51).
[184] Plaintiffs' skepticism apparently rests on their misimpression that each of Walmart's 4,000 pharmacies placed

scoff at undisputed facts; they must instead offer affirmative evidence. *See Celotex Corp.*, 477 U.S. at 322. Plaintiffs' skepticism runs headlong into three sets of hard, record facts. First, multiple witnesses confirmed that distribution center employees monitored for suspicious orders, while no witness testified the opposite. *See, e.g.*, Sullins Tr. 55:6-9; Abernathy Tr. 41:13-15. Second, the record contains documentary evidence of Walmart's monthly reporting to DEA.[185] Third, Walmart's distribution centers were audited by DEA throughout the relevant time period and were VAWD-certified starting in 2007, and neither DEA nor VAWD found Walmart's SOM systems non-compliant. *See, e.g.*, Dkt. 1866-45, 47, 53.

Finally, Plaintiffs argue in the alternative that "Walmart's policies and procedures failed to hold shipments of suspicious orders" during this period. Br. at 104. This alleged blanket "no ship" duty is unsupported by the CSA and irrelevant to Plaintiffs' common law claims. In any event, the evidence shows that Walmart complied with this alleged duty well before the beginning of the relevant limitations period. *See* Tongring Rpt. 6-7; Hiland 30(b)(6) Tr. 197:20-198:7. Plaintiffs' claims are thus contrary to the evidence—and far from undisputed.

F. Walgreens

Plaintiffs assert that Walgreens "failed to comply with its CSA duties to maintain effective controls against diversion." Br. at 105. Aside from the legal dispute about the scope of Walgreens' "CSA duties," the facts are plainly disputed. First and foremost, there is no diversion in Ohio related to Walgreens, so Plaintiffs' cannot show that Walgreens failed to maintain effective controls. Plaintiffs' SOM expert did not even try to identify evidence of

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orders for controlled substances on a daily basis. Br. at 101. But the record is clear that, during this time period, each pharmacy's Schedule II orders were filled only once per week, and not every pharmacy placed orders every week. *See* Hiland 30(b)(6) Tr. 55:6-10, 171:17-21. Moreover, Walmart only ever operated between 15 and 17 pharmacies in the two counties at issue in this proceeding. *See* Dkt. 1866-3 at 3, 5-6.

[185] *See, e.g.*, Ex. 112 (WMT_MDL_000044441-99); Ex. 113 (WMT_MDL_000046008-51).

diversion. Rafalski Tr. 508:1-12. He testified, "I don't have any direct knowledge of what happened to any of the drugs that were distributed to each of the pharmacies. I didn't conduct any analysis as of today that would give me that knowledge." *Id.* 582:9-19. He had nothing to say about Walgreens' customer base, or about differences in Walgreens' pharmacies that affect sales volume (*e.g.*, 24-hour locations, pharmacies near busy emergency rooms, on a corner lot, or with a drive-thru window). *Id.* 515:25-516:14. He did not even know how much oxycodone or hydrocodone had shipped to any Walgreens pharmacy. *Id.* 516:15-24.

Perhaps Plaintiffs failed to look at these aspects of Walgreens' business because they knew they would not support their case. Walgreens is no pill mill. It has a state-of-the-art SOM system, and a nationwide team of professional pharmacists, whose mission is to provide patients the medication they need, without allowing it to fall into the wrong hands. Walgreens has always taken this role seriously, and has always taken significant steps to prevent diversion, despite changing (or non-existent) guidance from DEA. All of this evidence shows, at a minimum, disputed facts that defeat Plaintiffs' motion.

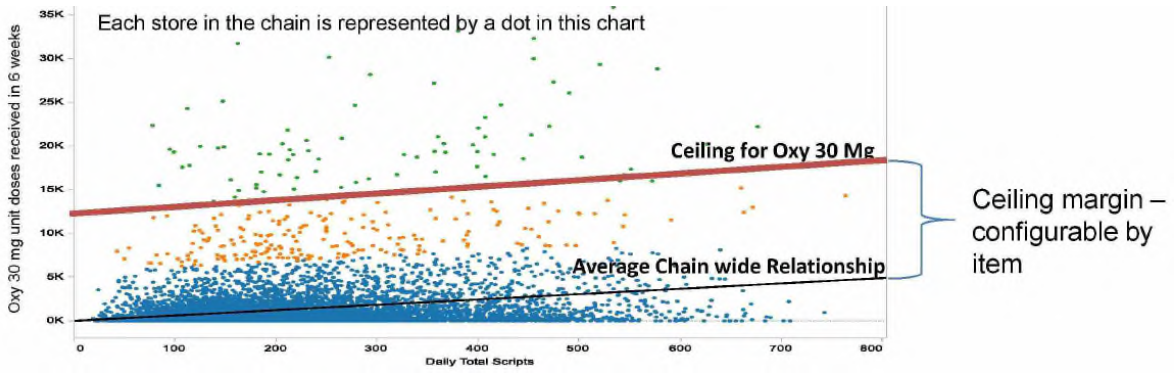
Lacking critical evidence of diversion in Ohio, Plaintiffs focus on a DEA action against Walgreens in Florida, in 2012, when changes in the law unique to Florida created a large influx of opioid prescriptions to all retail pharmacies. But the Florida action does not establish that Walgreens violated the CSA, either. Walgreens will show at trial that it has always maintained effective controls against diversion. To defeat Plaintiffs' summary judgment motion, however, Walgreens need only point to the many disputed facts described below.

1. Walgreens' SOM Systems Have Always Complied With DEA Regulations to Provide Effective Controls Against Diversion.

a. Walgreens' Current SOM System

Walgreens only ever distributed controlled substances to its own DEA-registered pharmacies—never to internet pharmacies, pain clinics, or other unaffiliated pharmacies.[186] Unlike third-party distributors, therefore, Walgreens controlled its pharmacies' policies and procedures, including policies on good faith dispensing and controlled substance reporting. Walgreens stopped ***all*** distribution of controlled substances into Ohio more than five years ago. Br. at 122. Even though it is no longer required to do so by law, Walgreens continues to operate its SOM system today, to protect against diversion.

Walgreens' SOM system is state-of-the-art. In place since 2012, the current system developed starting in 2008. It is the result of years of development by a cross-functional team from Prescription Purchasing, Logistics, Legal, Loss Prevention, and IT.[187] The system is based on a linear regression model.[188] It sets individual "ceiling limits" for every controlled substance at all Walgreens pharmacies. The limits are based on the relationship between (1) a store's daily prescription volume and (2) the volume of pills the store has received in the past six weeks:



[186] *See* Anderson Rpt. ¶ 48; *see also* Ex. 115, Customer Authentication Policy (WAGFLDEA00001746).
[187] *See* Ex. 116, Oct. 9, 2012 Controlled Substance Ordering Presentation (WAGMDL00667938 at 939-940); Ex. 117, Bancroft Tr. 24:12-27:16, 28:4-30:1, 31:13-33:4; Ex. 118, July 17, 2012 Presentation (WAGMDL00659828 at 845).
[188] *See* Ex. 119, Apr. 8, 2013 New Hire Documents (WAGMDL00245867 at 869); Ex. 116 at 940.

Ex. 116 at 941; *see also* Ex. 120, Jan. 2012 Polster DEA Update Market Leadership Meeting Presentation (WAGMDL00049753, at slide 14). Each order is also restricted by a "tolerance limit," which ensures that no individual order exceeds a given statistical limit based on a pharmacy's past order history. Ex. 119 at 869. The "ceiling" and "tolerance" limits are managed by the Pharmaceutical Integrity team, a multi-disciplinary group of pharmacists, data analysts, former law enforcement, and others tasked with preventing suspicious orders from being placed or filled.[189]

A store cannot place an order that exceeds either limit without seeking approval.[190] To do so, stores must submit a controlled substances override form, reviewed first by the store's management and then by the Pharmaceutical Integrity team.[191] The Pharmaceutical Integrity team may seek more information to determine, for example, if the store has a new patient with an unusual prescription, a hospice has opened down the street, or a nearby pharmacy has closed.[192]

If the Pharmaceutical Integrity department cannot determine that a pharmacy's request for additional controlled substances is justified, the request is denied. Until 2014, when Walgreens stopped distributing all controlled substances in Ohio, Pharmaceutical Integrity also reported such orders to DEA. *See, e.g.*, Bratton 30(b)(6) Tr. 274:1-6.

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[189] *See* Ex. 121, Daugherty Tr. 417:12-21 (Pharmaceutical Integrity team "manages flagged orders" and reviews orders for approval "if a store requests additional product"); Ex. 119 at 868; Ex. 122, Polster Dep. Ex. 4 (LinkedIn Page for VP of Pharmaceutical Integrity, former director of Pharmacy Operations and pharmacist); Ex. 123, Bratton Dep. Ex. 1 (LinkedIn Page for Manager of Pharmaceutical Integrity, former quality and analytics supervisor); Ex. 124, Daugherty Dep. Ex. 1 (LinkedIn Page for Manager of Pharmaceutical Integrity, former clinical operations pharmacy manager); Ex. 125, Stahmann Dep. Ex. 1 (LinkedIn Page for Manager of Pharmaceutical Integrity); Stahmann Tr. 11:23-13:12 (Dkt. 1971-2/1984-20) (testimony regarding law enforcement background); Ex. 126, Mills Dep. Ex. 1 (LinkedIn Page for Senior Business Analyst in Pharmaceutical Integrity).

[190] *See, e.g.*, Daugherty Tr. 420:23-422:24; Ex. 127, Merritello Tr. 108:7-20; Bratton 30(b)(6) 272:13-273:10 (Dkt. 1959-10/1975-9); Bratton Tr. 323:13-324:17 (Dkt. 1959-9/1975-10).

[191] *See, e.g.*, Bratton 30(b)(6) Tr. 268:14-22, 272:13-273:24.

[192] *See, e.g.*, Bratton Tr. 324:18-325:8, 325:22-327:6.

Plaintiffs assert that Walgreens' SOM system has "gaps or loopholes," such as failing to capture orders Walgreens pharmacies placed with other distributors. Br. at 116. But setting aside the fact that Walgreens has no obligation to monitor such orders—the other distributors bear that responsibility—Walgreens has continued to improve its SOM system to address any gaps.[193] More important, there is a fact dispute about whether any alleged gaps in the system allowed stores to increase their shipments of opioids "without being flagged and stopped." Walgreens' head of Pharmaceutical Integrity, Tasha Polster, testified that they did not.[194] And as discussed below, Walgreens always conducted due diligence to prevent shipping orders that were likely to be diverted.

b. Walgreens' Earlier Systems

Citing no evidence, Plaintiffs claim that "Walgreens knew" its pre-2012 SOM methods were "insufficient to fulfill its duties under the CSA." Br. at 111. In fact, what the evidence shows is that—just as Walgreens developed its current SOM system in response to DEA's changing informal guidance—Walgreens based its earlier systems on formulas DEA approved and recommended to distributors.

As early as 1988, DEA approved a Walgreens SOM method that was "based on an average monthly sales figure multiplied by an arbitrarily selected deviation factor."[195] DEA said using a formula like this was "one of the key elements in devising an effective reporting system."[196] Later guidance reiterated DEA's endorsement of similar SOM reporting methods.[197]

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[193] Polster Tr. 157:19-24 (Dkt. 1969-10/1983-7); Ex. 128 at 2 (Attachment to Pl. Ex. 364 noting "enhancements" to SOM system) (WAGMDL00325129-30).
[194] Polster Tr. 158:1-6.
[195] Ex. 129, Dec. 27, 1988 DEA Letter to Walgreens (US-DEA-00025683).
[196] *Id.*
[197] *See* Ex. 12 at -2230, -2247 (recommending a "DEA-approved Suspicious Order Monitoring System" based on a multiple of average purchase quantities); Ex. 130, 2004 DEA Chemical Handler's Manual at Appendix E-3 (WAGMDL00395965 at 6010) (similar formula for calculating "excessive or suspicious" orders).

Contrary to Plaintiffs' assertions, DEA made clear for decades that "[u]sing a computer to manage and report on high volume transaction business activities with extremely short order cycle times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious."[198]

That is exactly what Walgreens did: It reported thousands of orders to DEA using these "multiple of an average" SOM methods. *See* Br. at 107 & n.305. The fact that Plaintiffs' SOM expert identified other orders, using an algorithm unconnected to Walgreens' business, does not establish noncompliance with the CSA or regulations. Plaintiffs' argument that Walgreens was required to submit its "excessive purchase reports" to DEA ***before*** the orders shipped is contradicted by testimony from several DEA witnesses and DEA's own guidance that reports of "purchases" be provided "[a]t the end of each month."[199] Moreover, as part of the development of its current SOM system, Walgreens stopped shipping orders that exceeded the system's threshold limits in September 2010.[200] As Plaintiffs' SOM expert testified, those orders did not "have the potential to be diverted." Rafalski Tr. 367:22-368:13. Any failure to report could not have contributed to diversion. *Id.* at 370:15-371:23.

In addition, DEA audited Walgreens' distribution centers several times while Walgreens was using DEA's "multiple of an average" SOM systems, often without identifying any issues. When DEA asked Walgreens to make changes, Walgreens did so. As Plaintiffs' SOM expert acknowledged, "the environment of how diversion has occurred has changed over time. So I

[198] *See id.*
[199] *See supra*, Background Parts D, F; Ex. 130 at 6010; Mapes Tr. 92:1-25, 95:8-97:24 (DEA accepted excessive purchase reports "as compliant with the regulation for suspicious orders").
[200] Ex. 116 at 940 ("Automatic reductions to orders that exceed Tolerance threshold" began in September 2010).

think my experiences and my opinions on what would be required has changed over time because it's a fluid situation, not static." Rafalski Tr. 457:5-9.

For example, in May 2004, DEA audited Walgreens' Florida Distribution Center, and "their review did not identify any issues."[201] In May 2006, DEA audited Walgreens' Ohio Distribution Center, and concluded Walgreens' SOM formula was "insufficient." One month later, however, Walgreens advised DEA that it was "pursuing the necessary programming to modify this formula in accordance with the voluntary formula listed in Appendix E-3 of the DEA Chemical Handler's Manual."[202] By April 2007, the SOM system had been updated.[203]

Walgreens followed up with DEA repeatedly in 2007 and 2008—explaining that DEA had admonished Walgreens for ***not*** using the "multiple of an average" SOM system described in DEA's Chemical Handler's Manual—and asking for further guidance if DEA felt these revised methods were not in line with DEA's changing expectations.[204] In March 2008, after receiving the December 2007 Rannazzisi letter, Walgreens began development of its new SOM system.[205] It understandably took several years to design and implement that system across thousands of stores.[206] DEA set no deadlines.[207] Meantime, in an abundance of caution, Walgreens continued to report potentially suspicious orders using its existing system.

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[201] Ex. 131, Jupiter DC Audit (WAGMDL00757549).
[202] Ex. 132, July 28, 2006 Walgreens Letter to DEA (WAGMDL00387642); *see also* Ex. 133, Apr. 3, 2007 Soliva email (WAGMDL00400357) (reporting system was updated to comply with "latest DEA reporting requirements").
[203] *See* Ex. 133.
[204] *See* Ex. 134, June 25, 2007 Walgreens email to DEA (WAGMDL00387635); Ex. 135, Mar. 26, 2008 Walgreens email to DEA (WAGMDL00387651).
[205] Ex. 118 at 845; Ex. 136, June 24, 2008 Walgreens Proposal for Defining "Suspicious Orders" (WAGMDL00624527).
[206] Anderson Rpt. 69.
[207] *See supra*, Background Part G.

In 2009 and 2010, DEA audited Walgreens' distribution centers and again identified no issues with Walgreens' suspicious order monitoring of controlled substances.[208] Plaintiffs assert that "[t]here is no evidence that the DEA ever endorsed Walgreens' use of the post-shipment extraordinary size reports as its exclusive or primary SOM system." Br. at 111. But DEA's guidance as far back as 1988, Walgreens' repeated communications to DEA in 2007 and 2008, reiterating DEA's recommendation to use such methods, and DEA's subsequent audits of Walgreens in 2009 and 2010—finding no violations of the SOM regulation—is compelling evidence that DEA concluded Walgreens' SOM system was compliant in this period.

c. DEA's Florida Order Does Not Establish a CSA Violation.

Most of Plaintiffs' allegations against Walgreens focus on a 2012 Order to Show Cause and Immediate Suspension Order targeting a Walgreens' distribution center and six pharmacies in Florida for the volume of oxycodone they sold in 2010 and 2011. The Florida Order makes no reference to opioid distribution or dispensing in Ohio.[209]

As an initial matter, the Florida Order does not support Plaintiffs' motion because it is inadmissible hearsay.[210] The Order is an out-of-court statement, issued without any notice to Walgreens, much less a hearing on the merits. It is also untrustworthy. Walgreens vigorously disputed the allegations to the D.C. Circuit, arguing that they were "tainted by significant legal and factual errors," and faulting DEA for basing its Florida Order on "unreasonable assumptions and obsolete, year-old data."[211] By the time DEA issued the Florida Order, Walgreens had

[208] *See* Ex. 137, June 25, 2009 DEA Letter (WAGMDL00493683) (noting issues pertaining to "List 1 chemical products" but nothing about suspicious order monitoring of controlled substances); Ex. 138, Sept. 8, 2010 Coughlin email (WAGMDL00387641) ("Great news that the DEA just completed their on site review of Mt. Vernon [Distribution Center] and came away without any issues or citing of the operation.").
[209] The Florida Distribution Center had not distributed opioids into Ohio since 2007. *See* Br. at 110 n.327.
[210] Motions for summary judgment must be supported by admissible evidence. *See* FED. R. CIV. P. 56(c)(2).
[211] Br. of Petitioner at 1, 3, *Walgreen Co. v. DEA*, CV No. 12-1397, Dkt. No. 1411758 (D.C. Cir. Dec. 26, 2012).

reduced its volume of oxycodone prescriptions in Florida "dramatically"—a fact DEA acknowledged, and for which the D.C. Circuit criticized the agency.[212]

However, the Court need not determine here whether the Florida Order is admissible, because the Order does not establish that Walgreens violated the CSA. The facts are disputed.

The Florida allegations involved a period when Florida was addressing a crisis involving unscrupulous doctors dispensing opioids from pain clinics. In 2010, the Florida legislature virtually eliminated ***all*** physicians' authority to dispense Schedule II drugs directly to their patients from pain clinics—including the many doctors who prescribed ethically.[213] That change meant that every prescription that had previously been filled at a Florida pain clinic now had to be filled at a retail pharmacy.[214] As the head of the Florida Pharmacy Association acknowledged at the time, "[p]harmacies are struggling to deal with the influx of customers who used to rely on pain clinics to get controlled drugs."[215] Walgreens pharmacists regularly turned away patients with oxycodone prescriptions, gaining a reputation for taking a hard line against diversion.[216] As the Florida Order itself points out, Walgreens pharmacists also regularly notified law enforcement of attempted diversion at their stores. *See also infra*, Part II.F.2.c.

Plaintiffs claim that "Walgreens does not dispute that [the Florida Order] contains final findings of fact and conclusions of law." Br. at 108 n.312. That is untrue. Initial Suspension

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[212] *See* Ex. 139, Mar. 21, 2013 *Walgreen v. DEA* Hr'g Tr. 21-22; Ex. 118 at 847.
[213] *See* Ex. 140, July 18, 2012 Statement of Joseph T. Rannazzisi to the Caucus on International Narcotics Control at 6-7; Ex. 141, May 24, 2011 Statement of Michele M. Leonhart to the U.S. Senate Judiciary Committee, Subcommittee on Crime and Terrorism at 7. *See* 2010 Fla. Laws ch. 211, 20 (amending Fla. Stat. § 465.0276(1)(b) and restricting authority to dispense more than 72-hour supply to most patients); 2011 Fla. Laws ch. 141, 34 (amending same provision and ending authority to dispense in virtually all circumstances).
[214] Ex. 142, Declaration of DEA Counsel Scott Lawson ¶ 10, *In re Admin. Subpoena*, No. 1:12-mc-43 (E.D. Va. filed Nov. 16, 2012), ECF No. 34-2 (Ex. A to DEA Opp. to Mot. to Compel Return of Documents).
[215] Mar. 7, 2012 Timothy W. Martin & Arian Campo-Flores, *New Front Opens in Florida Pill War*, Wall St. J., at A6, available at http://online.wsj.com/ article/SB10001424052970203961204577267310025935508.html.
[216] Ex. 143, Apr. 6, 2012 Scott Hiaasen, *Walgreen Pharmacies Draw Scrutiny in Florida Pill Investigation*, The Miami Herald (Undercover law enforcement agents have "overheard nurses coaching pill-seeking patients to avoid bringing their prescriptions to Walgreen stores" and calling Walgreens "the enemy.").

Orders are not final "findings"; they are assertions, like allegations in a civil complaint, which must be proven, upon notice and a hearing. *See* 21 C.F.R. § 1301.37(c); 21 C.F.R. § 1301.44(e). The Florida Order was "final" only insomuch as it constituted final agency action which could be reviewed by the Federal Court of Appeals under 21 U.S.C. § 877. Plaintiffs' suggestion that by appealing the Florida Order, Walgreens conceded the allegations in it is completely false.

Plaintiffs also claim that Walgreens "admitted" it did not comply with the CSA in its settlement of the Florida allegations with DEA. Br. at 105. That, too, is false. Rather, Walgreens acknowledged that its Florida Distribution Center's "suspicious order reporting for distribution to ***certain pharmacies***"—none of which are in Ohio—"did not meet the standards identified by DEA in ***three letters from DEA's Deputy Assistant Administrator***." *Id.* (emphasis added). Again, DEA's informal "Dear Registrant" letters do not create legal requirements. By contrast, in the very same paragraph, Walgreens acknowledged that six of its Florida pharmacies "did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA (21 U.S.C. 801 et seq.)." Walgreens did ***not*** admit that its Florida distribution center had violated the CSA.[217] In any event, the settlement agreement is inadmissible under Federal Rule of Evidence 408 and therefore does not support summary judgment for Plaintiffs.

2. Walgreens Performed Multiple Levels of Due Diligence to Prevent Diversion of Opioids.

Plaintiffs assert that Walgreens performed no due diligence on suspicious orders. Br. at 107. Even setting aside the fact that the CSA and DEA regulations do not include a due

[217] Plaintiffs claim that DEA found Walgreens' alleged "violations" to be "systemic"—suggesting without evidence that the DEA was somehow alleging that every Walgreens distribution center and every Walgreens pharmacy had engaged in the specific conduct the DEA asserted in the Florida Order. No evidence supports that reading of the Order, and the absence of any reference in the Order to distribution or dispensing into Cuyahoga or Summit Counties suggests that DEA had no evidence of any such conduct that could have affected Plaintiffs.

diligence requirement, Plaintiffs ignore evidence of the substantial diligence Walgreens performed—at the distribution level, the corporate level, and the pharmacy level. This evidence shows disputes of fact requiring dismissal of Plaintiffs' motion.

a. Due Diligence at the Distribution Level

Walgreens distributions centers conducted regular due diligence on orders of controlled substances, to ensure that those orders were not likely to be diverted. For example, distribution center personnel ran a daily computer query to identify orders of unusual size.[218] Flagged orders were subject to a second query, focused on the pharmacy's ordering history.[219] Plaintiffs say these queries were "never meant to be used for SOM." Br. at 115. They may have been designed for a broader use, but Walgreens' witnesses testified these queries were also used to identify and prevent the shipping of unusually large orders.[220] Plaintiffs concede the policy on these queries was revised in 2010 to explicitly address suspicious order monitoring. Br. at 115.

Distribution center personnel also sought input from the inventory department, who, upon request, reviewed sales and order history for individual stores, to determine whether orders were unusual.[221] If so, the distribution center conducted additional research, typically including calls to the pharmacy to investigate. Diebert Tr. 146:17-25, 293:24-294:10. In fact, the manager of the Ohio Distribution Center had a phone installed in the controlled substances vault for just that purpose. Bish Tr. 484:2-24; *see id.* 479:21-482:2. As just one example of this type of diligence,

[218] Bratton Tr. 50:10-17, 82:17-84:23; Diebert Tr. 35:17-37:5 (Dkt. 1961-15/1976-15); Peterson Tr. 21:7-29:3 (Dkt. 1969-9/1983-6).
[219] *See* Diebert Tr. 35:17-37:5, 93:4-16; Bish Tr. 61:7-63:19 (Dkt. 1959-2/1975-2); Ex. 144, Dec. 11, 2006 Walgreens Rx Questionable Order Quantity Procedure (WAGMDL00757788); Ex. 145, Apr. 8, 2010 Rx Questionable Order Quantity Procedure (WAGMDL00751822).
[220] *See supra*, nn.218-219.
[221] *See, e.g.*, Martin Tr. 336:24-338:9 (Dkt. 1966-13/1981-7); Ex. 146, Martin Dep. Ex. 30 (WAGFLDEA00000846); *id.* Ex. 147, Jan. 11, 2011 Martin Email (WAGFLDEA00000852); Bish Tr. 63:12-16, 89:15-23, 485:1-19.

in a July 2010 email, a Walgreens pharmacy manager explained to her supervisor that "the warehouse called me to inquire about the growing orders of oxy 30 I have been placing, and said that it is a 'red flag' of sorts when a store orders more than 30 bottles per order."[222] In addition, "pickers" and "auditors" at the distribution centers reviewed orders to determine before shipping them whether they were unusual. Unusual orders were escalated to the manager for further review. Bish Tr. 482:4-484:8.

Finally, distribution center managers—those tasked with reviewing orders before they shipped—testified that they had "no personal knowledge of Walgreens ever shipping any orders of unusual quantities of controlled substances to Walgreens stores without first checking to see if those orders were justified," nor "any personal knowledge of Walgreens ever shipping controlled substances into any illegitimate channels." *Id.* 485:20-486:12. "[T]hey would have always been checked." *Id.* 486:3-5; *see also* Diebert Tr. 293:18-294:21. This evidence shows that, contrary to Plaintiffs' assertions, Walgreens' distribution centers conducted due diligence to prevent the shipping of orders that were likely to be diverted. *See* Anderson Rpt. 72, 91-92.

b. Due Diligence at the Corporate Level

Starting in 2012, the Pharmaceutical Integrity team conducted due diligence before approving orders beyond a store's "ceiling" or "tolerance" limit.[223] Prior to 2012, corporate personnel in inventory and loss prevention conducted due diligence. These employees reviewed sales and order history to determine whether orders were in line with a store's history or were unusual.[224] Starting in 2009, these employees reviewed reports of orders hitting on Walgreens'

[222] Ex. 148, July 8, 2010 Parlato Email (WAGFLDEA00000459); *see also* Bish Tr. 62-63, 481-482 (distribution center computer room verified with the pharmacy that orders were accurate "to make sure that what they wanted – what they ordered was what they intended to order and to make sure they really needed it").
[223] *See, e.g.*, Ex. 149, Aug. 2012 Controlled Substance Override Form (WAGMDL00107532); Ex. 150, Dec. 2012 Controlled Substance Override Form (WAGMDL00107162); *see supra* Part II.F.1.a.
[224] *See, e.g.*, Martin Tr. 336:24-338:9; Ex. 146 at 846, 852; Bish Tr. 63:12-16, 89:15-23, 485:1-19.

new SOM threshold limits, to determine whether the thresholds were set appropriately.[225] Based on these reviews, these employees provided input on adjusting the SOM system's parameters, as well as guidance to distribution center personnel on further diligence that needed to be performed.[226] This evidence shows that Walgreens performed diligence at the corporate level, to prevent orders from being diverted to illicit channels. *See* Anderson Rpt. 77-80.

c. Due Diligence at the Pharmacy Level

Finally, "Walgreens has always had a Good Faith Dispensing Policy."[227] Pharmacists are required to ensure that controlled substances are "only … dispensed to patients who have a prescription for a valid medical purpose issued by a practitioner acting in the usual course of professional practice."[228] Walgreens' dispensing policies include a number of steps pharmacists must follow before filling prescriptions for controlled substances. Since 2013, they have included extra steps for "target drugs" subject to abuse such as oxycodone.[229] Walgreens takes "a strict stance on compliance with these requirements," and failure to comply can lead to a pharmacist's termination of employment.[230]

Walgreens pharmacists refuse to fill prescriptions that they do not believe are legitimate. "Walgreens was the first in the industry to push back against prescribers that we felt were not writing prescriptions in good faith. We were the first to go on record publicly that we would not fill prescriptions."[231] Even before Walgreens implemented its Target Drug policies in 2013,

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[225] *See* Martin Tr. 23:20-24:11, 170:5-14, 328:5-329:7; *see also* Ex. 151, Martin Dep. Ex. 2 (WAGMDL00674550).
[226] *See, e.g., id.*; Martin Tr. 23:20-24:11; Bratton 30(b)(6) Tr. 160:1-161:7, 163:9-21, 210:12-211:24.
[227] Polster Tr. 93:13-94:3; *see also* Ex. 152, Feb. 7, 2007 Good Faith Dispensing Policy (WAGMDL00008112); Ex. 153, May 8, 2017 Good Faith Dispensing Policy (WAGMDL00005359).
[228] *Id.*; *see also, e.g.*, Daugherty Tr. 423:1-424:15; Bratton Tr. 137:17-138:8; Polster Tr. 93:13-96:10.
[229] Ex. 153; Ex. 154, Oct. 2, 2017 Target Drug Good Faith Dispensing Policy (WAGMDL00005369); Ex. 155, June 2018 Target Drug Good Faith Dispensing Checklist (WAGMDL00000360).
[230] Ex. 154.
[231] Polster Tr. 370:10-20 (VP of Pharmaceutical Integrity explaining Walgreens' dispensing practices circa 2013); *id.* 370:21-372:3; Ex. 156, American Medical Association Resolution 218 (AMA deemed "inappropriate inquiries

Walgreens pharmacists routinely refused to fill prescriptions they determined to be illegitimate.[232] Where warranted, pharmacists "will only fill if [patients] produce a drivers license matching name on rx, write down the diagnosis of patient on rx, and verify rx with Dr office." Ex. 148, July 2010 Parlato Email (WAGFLDEA00000459).

Walgreens pharmacists also routinely alert law enforcement to potential diversion:

- In 2009, two suspects were arrested at an Akron Walgreens due to a pharmacist's call to law enforcement over fraudulent prescriptions for Percocet and Xanax. Ex. 160, July 2009 Akron Police Report (AKRON_001158027-028).

- In 2013 and 2017, a Walgreens pharmacist in Summit County contacted Detective Patrick Leonard regarding suspicious prescriptions for controlled substances. Ex. 161, Nov. 2013 Akron Police Department Report of Investigation (SUMMIT_001520592-596); Ex. 162, Apr. 2017 Pancoe Email (AKRON_000367619).

- In 2015, a Walgreens pharmacist notified law enforcement of an attempt to fill an illegitimate prescription for Percocet at a Cleveland Walgreens. Ex. 163, May 2016 Cleveland Investigation (CUYAH_007488966-979).

- A Walgreens asset protection manager in Cleveland testified that she has worked with law enforcement, DEA, and the Ohio Board of Pharmacy, routinely over the past 12 years. Ex. 164, Zaccaro, Tr. 11:23-12:21, 17:4-22:1, 60:9-62:7.

Walgreens' DEA expert found that Walgreens performed "good due diligence," "above and beyond what is required in the CSA or the regulations." *See* Ex. 114, Anderson Rpt. at 73. Plaintiffs' ***own expert*** noted that Walgreens' Good Faith Dispensing Program is "a very good program" that "helped reduce opioid overprescriptions."[233]

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from pharmacies to verify the medical rationale behind prescriptions, diagnoses and treatment plans to be an interference with the practice of medicine and unwarranted").

[232] *See* Daugherty Tr. 426:16-427:1 (Pharmaceutical Integrity manager and former pharmacist testifying, "Q. If you couldn't confirm for yourself that a prescription was legitimate, would you fill it? A. No."); Ex. 157, Nov. 18, 2011 Healy Email regarding meeting with doctor whose prescriptions Walgreens refused to fill (WAGFLDEA00000763); Ex. 158, Sept. 18, 2011 Email regarding refusing to fill at store #12885 (WAGFLDEA00000401); Ex. 159, Aug. 26, 2011 Email regarding refusal to fill at store #05857 (WAGFLDEA00000443).

[233] Egilman Tr. 746:2-14 (Dkt. 1961-23/1977-2).

The evidence of Walgreens' due diligence is more than sufficient to demonstrate factual disputes requiring denial of Plaintiffs' motion as to Walgreens.

G. CVS

Plaintiffs' motion only pertains to CVS Indiana, L.L.C., which owns CVS's distribution center in Indianapolis.[234] Plaintiffs' contention that CVS Indiana "violated the CSA" is rife with factual disputes and all but ignores many of CVS's controls against diversion. Summary Judgment must be denied.

1. Irrelevant and Inadmissible Statements in CVS Settlements

Plaintiffs' lead claim is that summary judgment is warranted based on acknowledgements by CVS in two DEA settlement agreements. These statements are irrelevant. One involved dispensing by "certain" pharmacies in Florida. Pl. Ex. 384 at 3 ¶¶ I-K (Dkt. 1965-66). The other involved dispensing by "certain" pharmacies in Maryland. Pl. Ex. 382 at 2 ¶ G (Dkt. 1965-64). Neither involved Ohio. Neither involved CVS Indiana. Neither addressed any alleged noncompliance by any distribution center.[235] And regardless, the content of the settlements is inadmissible under Rule 408.[236]

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[234] The other CVS Defendant, CVS Rx Services, Inc., did not begin distributing controlled substances to Cuyahoga and Summit Counties until April 14, 2014. Ex. 165, Kwon Decl. By then, a new SOM system was in place. Vanelli Decl. (Dkt. 1889-4); Br. at 124 (explaining that "a new system was introduced in 2014"). Plaintiffs' motion does not challenge, or even discuss, this new system.

[235] While the release in the Florida settlement was broad and covered all CVS pharmacies and distribution centers in Florida, the statements cited by Plaintiffs and the allegations resolved in the settlement exclusively concerned the conduct of certain Florida pharmacies. Pl. Ex. 384 at 2-3 ¶¶ H-K ("DEA revoked the registrations issued to CVS stores 219 and 5195 … based … on their failure to fulfill their corresponding responsibility" in dispensing controlled substances; "The United States contends that CVS failed to fulfill its corresponding responsibility … and thus is subject to civil penalties"; "CVS acknowledges that certain CVS/pharmacy retail stores did dispense certain controlled substances in a manner not fully consistent with their compliance obligations").

[236] *See Hobart Corp. v. Dayton Power & Light Co.*, No. 13-cv-115, 2017 WL 5956911, at *21 (S.D. Ohio Nov. 30, 2017) (holding that Rule 408 barred "the content of prior settlement agreements"); *Mass. Mut. Life Ins. Co.*, 251 F. Supp. 3d at 332 (holding that Rule 408 barred defendant's prior settlement with DOJ and factual assertions acknowledged therein).

2. Facts Showing That CVS Indiana's SOM Systems Were Compliant

Plaintiffs assert that CVS Indiana's SOM systems in two different time periods (2006-2009 and 2009-2014) did not satisfy its duty to maintain effective controls against diversion. The record is replete with evidence to the contrary.

a. 2006-2009

From 2006 to 2009, CVS Indiana conducted suspicious order monitoring through employees in the distribution center's controlled substances cage. These employees received orders for controlled substances and then "picked and packed" the shipments. Wilson Tr. 11, 49 (Dkt. 1972-9/1985-21). They were trained to identify unusual orders and elevate them to their supervisors for further consideration. Wilson Tr. 12-18; Ex. 166, Nicastro Tr. 308; Millikan Tr. 132-33 (Dkt. 1968-1/1981-18). Additional review often included a call to the pharmacy that placed the order. Wilson Tr. 43-44; S. Hinkle Tr. 66-67, 70-72 (Dkt. 1963-2/1978-13); Vernazza Tr. 192-93 (Dkt. 1971-15/1985-7). Managers would then decide whether to ship or reject the order. Wilson Tr. 44.

Two employees reviewed each order. Wilson Tr. 26-27, 46; Hill Rpt. 17-18 (Dkt. 1939-13/1936-13). These employees were responsible for handling orders of controlled substances on a daily basis and were the "most knowledgeable" about whether an order appeared unusual. Nicastro Tr. 296-98. As one CVS employee who worked in the control cage for about 21 years testified: "You just know after you're in there day in and day out what's a big number." Wilson Tr. 62. The director of the CVS Indiana distribution center testified: "These were our experts." Nicastro Tr. 298.

While Plaintiffs criticize this system, DEA's Rule 30(b)(6) representative testified that manual SOM systems were appropriate. Prevoznik 30(b)(6) Tr. 179-80; *see also* Ashley Tr. 88. And when DEA inspected CVS Indiana's distribution center in 2006, it identified no deficiencies

in the SOM system. Hill Rpt. 15. DEA possessed the ARCOS data and never indicated to CVS that any of the orders it shipped to pharmacies in Cuyahoga and Summit Counties were suspicious. Hill Rpt. 25.

This evidence does not stand alone. Expert witness Robert Hill opined in his report that this system complied with the SOM regulation. Hill Rpt. 17-18. Mr. Hill worked at DEA for 25 years, and from 2009-2014, was a senior official in its Office of Diversion Control. *Id.* at 4-5.

CVS supplemented this system with several additional controls. ***First***, CVS did not distribute any controlled substance that DEA classified as Schedule II (*i.e.*, those substances with the highest potential for abuse). Vernazza Tr. 56; Kwon Rpt. 9-11 (Dkt. 1939-18/1936-18). It therefore never distributed opioids such as oxycodone or fentanyl. Kwon Rpt. 9-11. ***Second***, CVS distributed only to CVS pharmacies. Vernazza Tr. 56; Kwon Rpt. 7-9. It did not ship to pain clinics, independent pharmacies, or rogue internet pharmacies. Hill Rpt. 17.[237] ***Third***, on a monthly basis, CVS reviewed ordering patterns flagged by a computerized report called the Prescription Drug Monitoring Report (PDMR). Vernazza Tr. 166-68; Hill Rpt. 18. The report was an "anti-diversion tool" that tracked ordering, including order size and pattern. Vernazza Tr. 168-69, 178-79, 191.[238] Any concerns identified on the PDMR were investigated; approximately 150 employees were dedicated to this investigative role. Vernazza Tr. 166-67. "Although the PDMRs were generated monthly and could not have been used to identify suspicious orders in real-time, they complimented the real-time suspicious order monitoring program by providing for a monthly review of ordering patterns and by addressing circumstances of concern." Hill

[237] *See also* Ashley Tr. 249 (testimony of former DEA official: "[W]ould you also agree that the fact that these entities only shipped to their own pharmacies is a factor that should be taken into consideration when determining whether an order is suspicious? A. Yes, I believe that's a factor").

[238] The PDMR totaled the amount of a drug ordered by a pharmacy in a month, compared it to dispensing data to ascertain if ordering was outpacing what was needed to fill prescriptions, and provided data on whether the size of orders was impacted by manual adjustments at the pharmacy. Hill Rpt. 18-19; Vernazza Tr. 167-69.

Rpt. 18-19; Vernazza Tr. 167-70. In concluding that CVS's SOM system from 2006 to 2009 was compliant, Mr. Hill noted these additional controls. Hill Rpt. 16-19.

While Plaintiffs claim that CVS flagged too few orders, Mr. Hill opined that this was reasonable. Hill Rpt. 24-26. His opinion was based on, among other things, the fact that CVS did not distribute any Schedule II drugs, that it only distributed to CVS pharmacies, and that the CVS pharmacies in Cuyahoga and Summit Counties were "legitimate, everyday" pharmacies in good standing with DEA and the Ohio Board of Pharmacy. *Id.*

b. 2009-2014

In 2009, CVS supplemented its preexisting controls with an automated SOM system. Ex. 167, CVS-MDLT1-34192 at 192. Plaintiffs call this the "IRR system." Even with the addition of this system, CVS continued to use employees in the controlled substances cage to review orders for suspiciousness; it continued to restrict the drugs it distributed; it continued to restrict the customers to which it distributed; and it continued to review ordering patterns monthly through the PDMR.[239]

CVS hired a consultant—a former official in DEA's Office of Diversion Control—to design the IRR system. Hill Rpt. 20. The system used algorithms to evaluate each controlled substances order. Ex. 170, Choi Rpt. 14-15; Hill Rpt. 20. Orders that exceeded a certain score appeared on a daily Item Review Report (IRR). Burtner Tr. 69-70; Ex. 171 Mortelliti Tr. 40. Dr. William Choi opined in his expert report that "these algorithms, from a statistical standpoint, were a reasonable approach for identifying potentially suspicious orders." Ex. 170 at 3, 12-19.

[239] Vernazza Tr. 56; Millikan Tr. 92, 145-46; Burtner Tr. 310-11, 380-81 (Dkt 1959-13/1975-13); Helfrich Tr. 26, 29 (Dkt. 1962-28/1978-8); Hill Rpt. 19, 21; Ex. 168, CVS-MDLT1-3028 at 3029-30; Kwon Rpt. 7-11; Ex. 169, CVS-MDLT1-74775 at 4778.

Analysts reviewed the IRR every day and conducted any additional investigation they believed necessary—for instance, by calling the pharmacist that placed an order or by reviewing additional data. Burtner Tr. 521-22; Helfrich Tr. 196, 245-46; Mortelliti Tr. 54; Vernazza Tr. 394-95. Orders flagged on the IRR report were not shipped unless they were cleared by the analysts. Hill Rpt. 22; Burtner Tr. 334; Ex. 172, CVS-MDLT1-109871 at 871-72. If an order was deemed suspicious, it was not shipped, and it was reported to DEA.[240]

The analysts testified that they had the time and resources to conduct the due diligence that they thought necessary. Burtner Tr. 522; Ex. 175, Baker Tr. 366-67. They further testified that they never let a possibly suspicious order ship. Helfrich Tr. 248; Burtner Tr. 523. For several months, CVS engaged yet another former DEA official and his firm to assist the analysts in their review. Ex. 176, Vanelli Tr. 234-36; Helfrich Tr. 224; Hill Rpt. 22; Ex. 177, CVS-MDLT1-104918.

In 2012, CVS engaged a third former DEA official to conduct a real-time review of the system. Hill Rpt. 22-23. This consultant spent three days on-site and met with the analysts. Ex. 178, CVS-MDLT1-125136 at 139. He concluded that the system was "effective." *Id.* at 148. Expert Robert Hill also assessed the IRR system and concluded it was compliant. Hill Rpt. 19-23.

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Plaintiffs have not—and cannot—meet their burden. CVS had layers of controls in place to detect suspicious orders and prevent diversion. It prohibited shipments of Schedule II drugs. It prohibited shipments to non-CVS pharmacies. It had multiple employees review orders and

[240] Ex. 172, CVS-MDLT1-109871 at 871-72; Hill Rpt. 22; Ex. 173, CVS's Written Responses to Topics 8, 9, 12, 13, and 14 of Plaintiffs' Amended Second Notice of Deposition Pursuant to Rule 30(b)(6) at 3; Ex. 174, CVS-MDLT1-75300 at 306, 311; CVS-MDLT1-3028 at 3029.

ordering patterns. It used computer algorithms. And it relied on former-DEA officials to help guide their systems. This evidence alone defeats summary judgment.

3. Facts Disputing Particular Allegations Against CVS

a. Expert Witness Robert Hill

Plaintiffs claim, in a footnote, that Mr. Hill's expert opinions are invalid. They say that he neglects to apply the definition of suspicious orders in the SOM regulation. But Mr. Hill's opinions are expressly based on that regulation and the definition it contains. Hill Rpt. 9-10, 12.[241] Notably, Plaintiffs filed no *Daubert* motion challenging Mr. Hill's opinions.

b. Due Diligence in the IRR System

Plaintiffs contend that CVS "investigated" only a small number of orders that flagged on the IRR. But CVS's SOM analysts testified that they "reviewed every order on the IRR on a daily basis." Burtner Tr. 521-22; Helfrich Tr. 245-46; Millikan Tr. 194-96. The IRR identified the drug ordered, the size of the order, and the store that ordered it. Hill Rpt. 20. It also contained information about the store's ordering history. *Id.* Reviewing the IRR was itself due diligence. Burtner Tr. 95, 492; Helfrich Tr. 247; Hill Rpt. 20. This was on top of the review of each order conducted by the employees in the controlled substances cage.

Plaintiffs rely on documents that track instances when "additional" investigation, beyond the IRR, was conducted. Br. at 125. Those documents do not suggest that each order on the IRR was not reviewed. "[E]very order" on every IRR was reviewed by SOM analysts, Burtner Tr. 521-22, and was separately reviewed in the controlled substances cage.[242]

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[241] While Plaintiffs cite Section V.D of Mr. Hill's report in arguing that his definition of suspiciousness deviates from the regulation, that section does not propose a different definition. It merely states that "[t]he purpose of suspicious order monitoring is not to halt or limit the number of prescriptions being written in good faith by legitimate medical practitioners" and that "[i]t is appropriate for a distributor to fill a steady increase in orders that result from an increasing volume of prescriptions written in good faith by medical practitioners." Hill Rpt. 13-14.

[242] Notably, the documents cited by Plaintiffs—IRR Recaps—show that CVS conducted "additional" investigation,

c. "Noncompliant" Reference in IT Request From

Plaintiffs cite a document regarding a technical glitch found in the IRR system in 2010 triggered by changes in drug names. Hill Rpt. 27-28. They contend that the document is proof that the IRR was "flawed." The document (a request for IT assistance) states that the "IRR loses all order history when the info on the item changes causing CVS to be non compliant with DEA expectations." Pl. Ex. 411 (Dkt. 1947-93). But the analyst who wrote it testified that "we were compliant" and he "worded" the IT request "to get it pushed through the system." Mortelliti Tr. 135. More significantly, the analyst testified that he was able to obtain the missing information from other sources and therefore compensated for the IRR glitch until it was corrected. Mortelliti Tr. 151-52. Expert witness Robert Hill considered the document cited by Plaintiffs and the surrounding evidence. He opined that Plaintiffs' position on it was "unfounded." Hill Rpt. 27-28.

d. DEA Compliance Coordinator

Plaintiffs contend that the DEA Compliance Coordinator (from 2008 to 2014) testified that she did not do that job. Incorrect. She testified that she submitted ARCOS data, was a liaison between the distribution centers and corporate, and served as a central contact for standard operating procedures. Propatier Tr. 56, 80-81, 128 (Dkt. 1969-16/1983-13). Other individuals were responsible for coordinating SOM. Ex. 180, P. Hinkle Tr. 22; Mortelliti Tr. 17-18.

e. Outside Vendor Orders

Plaintiffs contend the algorithms underlying the IRR did not consider data on past orders shipped to pharmacies by outside vendors (OVs). But CVS reviewed OV orders in the PDMR,

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beyond the IRR, on more than 5,400 orders in the 30 months covered by the documents. While Plaintiffs suggest that one of the SOM analysts conducted "additional" investigation on only seven orders during a 12-day period in 2012, the portion of the IRR he reviewed flagged no hydrocodone combination product (HCP) orders—the only relevant opioid CVS distributed. Ex. 179, Hynes Decl.

and the analysts could access these orders during their daily review. Burtner Tr. 284. Mr. Hill considered Plaintiffs' position on OV orders and determined it was not valid. Hill Rpt. 28-29.[243]

f. Written Policies

Plaintiffs argue that CVS did not have written SOM policies until after 2009. But neither the CSA nor its implementing regulations require written policies. Hill Rpt. 27; Prevoznik 30(b)(6) Tr. 358-59. As set forth above, CVS had controls in place throughout the entire relevant period (2006-2014). The absence of a writing before 2010 does not in any way render CVS's pre-existing systems non-compliant. Hill Rpt. 27; Prevoznik 30(b)(6) Tr. 358-59.

H. Rite Aid

Plaintiffs ask this Court to rule as matter of law that Rite Aid of Maryland, d/b/a Mid-Atlantic Customer Support Center ("Rite Aid," or "Rite Aid Mid-Atlantic")—the only Rite Aid entity named as a Defendant—breached a duty to maintain effective controls against diversion of opioids. Plaintiffs' arguments fail both legally and factually. Indeed, as set forth in Rite Aid's individual motion for summary judgment, the absence of evidence entitles Rite Aid to summary judgment on the same issue.

1. Plaintiffs' Motion Should Be Denied Because They Fail To Present Expert Testimony Regarding Rite Aid's Suspicious Order Monitoring System.

With respect to Rite Aid, Plaintiffs' motion relies entirely on attorney argument. Br. at 126-132. Plaintiffs proffer no expert testimony criticizing, in any way, Rite Aid's suspicious order monitoring system. This failure is fatal: "Unless a matter is within the comprehension of a

[243] In discussing OVs, Plaintiffs cite a page from a CVS PowerPoint on "reporting requirements." Pl. Ex. 407 at 8 (Dkt. 1947-89). It states that CVS must report to DEA within 24 hours any orders placed to its own distribution centers that it determines to be suspicious. *Id.* It distinguishes this scenario from orders placed with an OV. In that instance, the reporting requirement does not run to CVS. Instead, under § 1301.74(b), it runs to the OV. Plaintiffs' motion cites no evidence that CVS ever identified a suspicious order to an OV, much less that it failed to respond appropriately to such an order. In the scenario posited in the PowerPoint, the PowerPoint makes clear that CVS would not allow the store to place orders until all concerns are addressed. *Id.*

layperson, expert testimony is necessary." *Ramage v. Cent. Ohio Emergency Servs., Inc.*, 592 N.E.2d 828, 833 (Ohio 1992).

This principle requires expert testimony regarding the adequacy of a SOM system. A lay juror has no knowledge or experience regarding distribution of opioids, reasonable practices regarding the monitoring of suspicious orders and the prevention of diversion, or the regulatory framework that governs these practices. Indeed, Plaintiffs effectively concede the point by designating experts to testify regarding other Defendants' suspicious order monitoring systems. *See* Rafalski Rpt. (Dkt. 2000-22/1999-21); Whitelaw Rpt. (Dkt. 2000-26/1999-25). Expert testimony must "help the trier of fact to understand the evidence or to determine a fact in issue." FED. R. EVID. 702(a). By arguing that Rafalski and Whitelaw's testimony would be helpful to the trier of fact, Plaintiffs necessarily acknowledge that lay jurors need help and cannot evaluate suspicious order monitoring systems based on their general experience.

The deadline for expert designations has long passed. Plaintiffs' failure to offer expert testimony regarding Rite Aid's suspicious order monitoring system requires granting Rite Aid's summary judgment motion and denying Plaintiffs' motion.

2. Plaintiffs Fail To Identify Any Suspicious Orders Shipped By Rite Aid.

Independently, Plaintiffs cannot receive summary judgment regarding breach because they fail to identify any evidence that Rite Aid distributed any suspicious orders. Plaintiffs' motion conflates orders **distributed to pharmacies** by Rite Aid Mid-Atlantic (the Defendant) with prescriptions **filled by pharmacies** owned by Rite Aid of Ohio (which has not been sued). Plaintiffs' motion focuses exclusively on prescriptions **filled by** pharmacies. *See* Br. at 128-129 (arguing that Rite Aid failed to "identify or report . . . suspicious orders [*i.e.*, prescriptions] from those suspicious prescribers"); *id.* at 129 (alleging that "Rite Aid identified zero suspicious orders [*i.e.*, prescriptions] from Dr. Harper's customers").

But Rite Aid Mid-Atlantic is only—and has only been sued as—a distributor. Evidence that a pharmacy filled an allegedly improper prescription is not evidence that the pharmacy placed a suspicious order with the distributor. Any diversion that occurred at a pharmacy may—or may not—have caused the pharmacy to place a suspicious order with a distributor. Plaintiffs' liability theory requires them to prove that Rite Aid Mid-Atlantic distributed suspicious orders to pharmacies. Plaintiffs' summary judgment motion identifies no evidence that this occurred.

Indeed, Plaintiffs' arguments based on allegations that pharmacies filled improper prescriptions conflict with their prior representations to this Court. Plaintiffs represented that they were suing Pharmacy Defendants only in their capacity as distributors: "Plaintiffs do not allege violations of statutes or regulations applicable specifically to retailers who sell opioids." Dkt. 59 at 75 n.47. And Plaintiffs expressly represented that they would not challenge any specific prescription: "Plaintiffs do not intend to assert, either in expert opinions or factual presentations at trial, that any specific prescription was unauthorized, medically unnecessary, ineffective, or harmful[.]" Dkt. 1058 at 3. Having limited their claims, Plaintiffs cannot now change their theory of liability after the close of discovery, and the portion of their motion based on arguments about allegedly unauthorized or unnecessary prescriptions should be disregarded.

3. Rite Aid Maintained Effective Controls Against Diversion.

Plaintiffs' motion also fails factually. Rite Aid's distribution system was fully capable of identifying and reporting any suspicious orders. The absence of suspicious orders is a testament to Rite Aid's effective controls against diversion, its small market share, and the fact that it never distributed Schedule II drugs.

a. Reporting No Suspicious Orders Is Not Evidence That Rite Aid Failed To Monitor for Suspicious Orders.

Rather unusually, Plaintiffs seek summary judgment based primarily on the absence of evidence. Br. at 126. That Rite Aid did not report any suspicious orders, Plaintiffs say, is proof that Rite Aid had an inadequate suspicious monitoring system. *Id.* The absurdity of this reasoning is readily apparent.

As Plaintiffs acknowledge, Rite Aid distributed opioids only "to its own Rite Aid stores." Br. at 127; *see also* Belli Tr. 20:13-16 (Dkt. 1956-20/1974-20); Ex. 201 Chapman Tr. 35:7-11. Rite Aid never distributed directly to internet pharmacies or to any doctors—"'pill mill' doctors," "suspicious prescribers," or otherwise. Nor did Rite Aid ever distribute Schedule II drugs—such as oxycodone or fentanyl.

Rite Aid's distribution pattern stayed flat or decreased until it stopped distribution in September 2014. In contrast to the increased opioid distribution to which Plaintiffs' experts attribute the opioid crisis—Cutler Rpt. ¶ 50 (Dkt. 2000-4/1999-4); Gruber Rpt. Section III (Dkt. 1999-6/2000-6)—Rite Aid's opioid distribution into Summit and Cuyahoga Counties remained steady over the relevant time period and consistent with its distribution of non-controlled substances. Jena Rpt. ¶¶ 50-52 (Dkt. 1939-15/1936-15).

Rite Aid distributed only a small portion of any opioids: **0.048%** of morphine milligram equivalents ("MMEs") distributed into Cuyahoga and Summit Counties from April 25, 2014 to April 25, 2018 (the limitations period) and **0.71%** of MMEs distributed from 2006 to 2014. Jena Rpt. ¶ 49; Jena Decl. ISO Rite Aid Mot. Summ. J. (Dkt. 1870-2/1888-2).

Given Rite Aid's limited distribution of a small percentage of opioids into its own stores and its numerous controls against diversion, it should come as no surprise that Rite Aid identified no suspicious orders during the relevant time period.

b. Rite Aid Maintained Effective Controls Against Diversion of Opioids.

Contrary to Plaintiffs' unsupported argument (at 126), Rite Aid consistently maintained a system to identify and report suspicious orders. *See* Rite Aid policy (Dkt. 1965-94/1974-94); *see also* Hart 30(b)(6) Tr. 26:3-11 (Dkt. 1962-22/1978-2). Rite Aid's policies required review to determine legitimacy of orders, reporting of suspicious orders to the corporate office, notification to DEA, and determination by Corporate Government Affairs whether or not to ship the order. Rite Aid policy (Dkt. 1965-94/1974-94); *see also* Hart Tr. 102:6-10 (Dkt. 1962-21/1978-1).

i. Rite Aid's suspicious order monitoring system would detect and prevent orders of unusual size or of an unusual pattern.

Rite Aid's suspicious order monitoring system included multiple safeguards to detect and prevent orders of unusual size. Order quantity was determined in the first instance by the computerized "auto-replenishment system" administered by Rite Aid Hdqtrs Corp., which placed orders to the distribution center based on an algorithm that took product sales and on-hand inventory over a 13-week period into account. Chapman Tr. 42:13-16. Pharmacists had only a limited ability to manually override the quantity determined by the algorithm, *i.e.*, no order could be greater than 60% more than the largest order in the past 13 weeks. Hart 30(b)(6) Tr. 77:9-21, 275:19-276:1. Rite Aid's auto-replenishment system thus prevented orders from deviating substantially from a normal pattern. Additionally, absent rare exceptions, Rite Aid refused to distribute any order exceeding 5,000 dosage units. Chapman Tr. 70:14-17; Hart 30(b)(6) Tr. 92:10-14.

Plaintiffs state that only orders above this 5,000-unit threshold were verified. Br. at 127. This is false. Employees were trained and instructed to identify and verify the validity of any unusual order, regardless of whether those orders were below the threshold. *See* Controlled Drug

Above Average Order Monitoring Program, Rite_Aid_OMDL_0015079-81 (Dkt. 1947-95/1965-95). Based on years of experience filling orders for the same stores, staff at the distribution center were well-positioned to detect orders that appeared unusual. *See* Belli Tr. 67:15-19 ("[T]hey knew the stores very well."); Hart Tr. 11:8-22 ("[Employees] know the previous store's history from picking the order every week."). Distribution center staff thus verified any order—even those below the threshold—that "seem[ed] high or unusual" and recorded it in the log. *See* Controlled Drug Above Average Order Monitoring Program, Rite_Aid_OMDL_0015079-81; *see also* Wood Tr. 112:20-23 ("[I]f it just seemed unusual, we would log that as well."), 113:24-114:8 ("Sometimes it just seemed too high for what that item was picking that day.") (Dkt. 1972-10/1985-22). These logs include notes on calls placed to the pharmacy and any other actions taken with respect to those orders. *See, e.g.*, Ex. 181, Threshold Log (Rite_Aid_OMDL_0024037-38); Ex. 182, Threshold Log (Rite_Aid_OMDL_0015876-77). Rite Aid's corporate headquarters also reviewed the logs for potential abnormalities. Belli Tr. 91:16-92:11; Hart Tr. 166:21-167:3.

ii. Rite Aid's suspicious order monitoring system prevented orders of unusual frequency.

Plaintiffs argue (at 131) that Rite Aid's distribution center staff did not monitor for orders of unusual frequency. But Rite Aid's controls prevented such orders from being placed in the first instance. The frequency of orders from Rite Aid of Ohio pharmacies to the Rite Aid Mid-Atlantic distribution center was determined by Rite Aid Hdqtrs based on store volume and storage space and was implemented by the auto-replenishment system. This frequency—once a week for most stores, twice a week for some, or every two weeks for others, Hart 30(b)(6) Tr. 79:23-80:14, 82:11-83:18—could not be overridden at the pharmacy level. Wood Tr. 118:4-8 ("[The corporate system] would determine the frequency[.]"). As a result, the pharmacies could

not change the frequency of orders placed to the distribution center. Rite Aid's auto-replenishment system thus prevented any orders of unusual frequency.

iii. Rite Aid's effective anti-diversion measures included post-shipment investigations.

As Plaintiffs acknowledge, "[a]fter the orders had shipped, Rite Aid monitored its inventory through its Navicase/Naviscript system." Br. at 127. "The Rite Aid Asset Protection Department used 'key performance indicators' (KPIs) to analyze data about ordering from the Rite Aid stores to identify diversion through theft." *Id.* Collecting and analyzing KPI data permitted Rite Aid to detect and investigate potential theft and diversion at the pharmacy level. Ex. 183, Palmer Tr. 161:2-6; s*ee also* Hart 30(b)(6) Tr. 49:2-9, 49:23-50:7, 130:9-131:16 (explaining how analysis of KPIs in Asset Protection is used to prevent diversion).

Indeed, the two instances of diversion cited by Plaintiffs (at 129-30) were both detected by Rite Aid and reported to DEA and the Ohio Board of Pharmacy. Far from supporting Plaintiffs, these examples confirm the effectiveness of Rite Aid's anti-diversion measures. *See* Ex. 184, "Anatomy of a Pharmacy Case" presentation (Rite_Aid_MDL_0037816-51) (discussing how Rite Aid detected Kozik's theft); Ex. 185, Kins Incident Report (Rite_Aid_OMDL_0044599-601) (Rite Aid incident report for Kins).

c. Rite Aid's Suspicious Order Monitoring System Was Audited and Commended by DEA and State authorities.

Audits further confirmed the controls' effectiveness. In 2005, 2009, and 2012, DEA audited Rite Aid Mid-Atlantic (including its suspicious order monitoring system) and it passed with flying colors each time.[244] In 2012, DEA specifically praised Rite Aid's suspicious order monitoring program: "Both DEA inspectors are very impressed and pleased to see that Rite Aid

[244] In a pending motion, Rite Aid seeks to compel DEA to produce all documents pertaining to its audits and to make available for testimony Don Tush, a DEA inspector involved in the audits.

demonstrates its due diligence by having an excellent excessive order monitoring program." Rite_Aid_OMDL_0012548 (Dkt. 1870-3/1888-3, at page 55); *see also, e.g.*, Mitchell Tr. 212:20-313:6 (Dkt. 1968-4/1981-21) ("DEA as well commented on just how good and solid that program was."); Ex. 186, Frost Tr. 87:19-88:6 ("[T]hey were very, very happy with the way we had our controls in place, and they wished other places did the same thing we did."). Audits by the Maryland Board of Pharmacy and Maryland Division of Drug Control reached similar conclusions. *See* Audit Reports (Rite_Aid_OMDL_0032622-28, Rite_Aid_OMDL_0032614-17, Rite_Aid_OMDL_0032629-33, Rite_Aid_OMDL_0036784-87) (Dkt. 1870-3/1888-3 at 68-87).

d. Plaintiffs' Remaining Arguments Are Meritless.

Plaintiffs' remaining arguments misstate the evidence. Plaintiffs assert that Rite Aid first "sought to develop a suspicious order monitoring system" in 2013. Br. at 132. In truth, that project was designed to consolidate Rite Aid's existing suspicious order monitoring system:

> **[T]hose controls were already in place**. So the effect of this project was basically to display them in one place. So we had—this project was not created to create [sic] effective controls. . . . This was simply, as I stated earlier, just bringing them in a easily [sic] format to display.

Belli Tr. 160:10-19 (emphasis added); *see also* Chapman Tr. 113:23-114:15 ("fold[] all of those processes together"); Hart 30(b)(6) Tr. 227:3-7 ("[M]ake sure that everything was in one place.").

Plaintiffs also misleadingly discuss Dr. Adolph Harper, who they call "a notorious convicted pill-mill doctor." Br. at 129. Rite Aid played a key role in enabling the prosecution of Dr. Harper. Detective Patrick Leonard, the lead investigator, testified that a Rite Aid pharmacist provided a tip to investigators in January 2011. Ex. 187, Leonard Tr. Vol. II 258:15-261:1; Leonard Tr. Vol. III 391:18-22 (Dkt. 1966-3/1979-18). It was more than a year later, in May 2012, that Dr. Harper voluntarily surrendered his license to prescribe controlled substances.

Leonard Tr. Vol. II 266:11-267:5; Ex. 188, Exhibit 21 to Leonard Deposition. During the course of the investigation, Detective Leonard neither warned pharmacies not to fill prescriptions by Dr. Harper nor instructed distributors not to distribute to these pharmacies. Leonard Tr. Vol. III 392:21-393:15.[245]

Plaintiffs' motion also misleadingly describes an industry-leading practice by Rite Aid Hdqtrs Corp., the identification and shutting off of certain prescribers under its "Prescriber Review" program, as an alleged failure to "report suspicious orders from those suspicious prescribers." Br. at 128-29. Again, Plaintiffs conflate dispensing—which they have expressly disavowed as a basis for claims—with distribution. The Prescriber Review program enhanced controls related to *dispensing* prescriptions—it had nothing to do with Rite Aid Mid-Atlantic's obligations as a *distributor*. *See* Hart 30(b)(6) Tr. 154:2-13, 167:12-168:6. Doctors did not place "orders" to Rite Aid Mid-Atlantic, and Rite Aid Mid-Atlantic did not ship orders to doctors. There were no "suspicious orders" from those prescribers for Rite Aid Mid-Atlantic to report.

Finally, Plaintiffs reference "suspicious orders evidenced in a DEA Settlement." Br. at 126, 130. But that settlement concerned pharmacy level activity (primarily recordkeeping); did not involve distribution practices or any distribution center; did not relate to suspicious order monitoring; had nothing to do with Ohio; and involved no admission of liability. Hart 30(b)(6) Tr. 193:18-21, 197:4-8; Hart Tr. 68:12-14. Plaintiffs' misplaced reliance on this settlement only confirms the absence of any actual evidence of any breach by Rite Aid Mid-Atlantic.

Plaintiffs' motion for summary judgment should be denied and Rite Aid's granted.

[245] The document Plaintiffs cited (at 129) referring to Dr. Harper is an email exchange concerning a threshold increase requested of McKesson, which has nothing to do with Rite Aid Mid-Atlantic. And in October 2011, both Rite Aid and McKesson declined to approve a pharmacy's request for a threshold increase based on increased activity from Dr. Harper. Ex. 189, Emails regarding Dr. Harper (MCKMDL00626683-5).

I. HBC/Giant Eagle

Unable to offer any expert testimony that Giant Eagle did anything wrong, Plaintiffs rely on obfuscation to create the illusion of wrongdoing. For starters, Plaintiffs suggest that HBC was a McKesson-like distributor that shipped to unaffiliated customers in arms-length transactions. It did not. As a mere operating division of Giant Eagle, Inc. ("Giant Eagle"), HBC distributed controlled substances only to Giant Eagle's in-store pharmacies.[246] Plaintiffs also claim that HBC was a large distributor of opioids in Cuyahoga and Summit Counties (the "Counties"). It was not. HBC distributed only one drug relevant to this litigation—HCPs—and, during its brief distribution of that product (from November 2009 and September 2014), HBC had less than one-percent market share in the Counties. Finally, Plaintiffs fail to disclose to this Court an inconvenient fact that undermines their claim that Giant Eagle violated the CSA—that despite regular audits and inspections the DEA never fined or brought any enforcement action against Giant Eagle.

With no evidence to support their position, Plaintiffs pin all their hopes on the mistaken ipse dixit proclamations of their lawyers. For example, while Plaintiffs allege that "orders of unusual size were regularly… shipped into Cuyahoga and Summit Counties," they do not identify even one such order. Plaintiffs claim that Giant Eagle's SOM system was not "meaningful" yet they offer no expert testimony to support that claim or rebut the ample testimony from Giant Eagle's experts that its SOM system fully complied with DEA regulations. Plaintiffs even claim that Giant Eagle had no SOM system in place before 2014 when, in fact, it

[246] HBC warehouses and supplies general merchandise to Giant Eagle grocery stores. In January 2016, Giant Eagle opened a new warehouse that was a separately licensed unincorporated division known as Giant Eagle Rx Distribution Center ("GERXDC"). GERXDC started distributing Schedule II-V controlled substances to Giant Eagle Pharmacies in March 2016. Plaintiffs' allegations and discovery efforts in this case have focused on Giant Eagle's HBC facility. Based on Plaintiffs' motion, it is now clear that this lawsuit wholly targets distribution activities originating at Giant Eagle's HBC warehouse between 2009 and 2014.

had an extensive system of integrated controls against diversion from the moment HBC began distributing drugs to Giant Eagle's pharmacies. Though Giant Eagle added an additional control in the form of a threshold system, it proved to be unnecessary and only confirmed the effectiveness of its existing anti-diversion system.

1. Giant Eagle's SOM System Always Complied With DEA Regulations by Providing Effective Controls and Procedures to Guard Against Theft and Diversion.

Plaintiffs claim three sources of purported "undisputed evidence" show that Defendants failed to comply with the CSA: (1) "Plaintiffs' expert report analyzing the Defendants' SOM programs and their compliance with the CSA"; (2) "Defendants' communications with the DEA"; and (3) "Defendants' internal documents concerning their SOM programs." Br. at 25. Not so. To the contrary, even the most cursory review of relevant documents and testimony shows that the Court should instead grant Giant Eagle's motion for summary judgment. *See* HBC's Mem. in Support of Summ. J. (Dkt. 1912/1923) ("HBC Mem.").[247]

a. "Plaintiffs' Expert Report[s] Analyzing the Defendants' SOM Programs" Say Nothing About Giant Eagle.

Whether an industry participant has violated the DEA's SOM regulations is not a subject within the common understanding of a lay juror. *See* HBC Mem. at 10-13; *see also, e.g.*, *Montgomery v. Gooding, Huffman, Kelly & Becker*, 163 F. Supp. 2d 831, 836 (N.D. Ohio 2001);

[247] The "Background Facts" in the opening of Plaintiffs motion (see pages 3-25) are similarly inapplicable to Giant Eagle. Despite the suggestion that these "Facts" apply to generally to "Defendants," the undisputed record shows that HBC (1) has never been the subject of *any* DEA enforcement action, *see, e.g.*, Carlson Tr. 222:24-223:16 (Dkt. 1959-18/1975-18); Mollica Tr. 60:3-61:3 (Dkt. 1968-5/1982-1); (2) has never been a member of NWDA, HDMA, or HDA, Ex. 190, Interrog. Resp. No. 7; (3) has never filled any order with reason to believe that it was destined for any illicit market, *see* Tsipakis 30(b)(6) Tr. 22:22-23:9 (Dkt. 1971-12/1985-4); (4) did not receive Mr. Rannazzisi's 2006 or 2007 Dear Registrant Letters, *see* Tsipakis 30(b)(6) Tr. 15:11-16:3 (showing HBC was not a registrant until 2009); and (5) has never failed to comply with the CSA, Greimel Rpt. 15 (Dkt. 1939-12/1936-12); Am. Kinsey Rpt. 9-10 (Dkt. 1939-17/1936-17). Plaintiffs' motion presents no evidence to the contrary and never even identifies HBC or Giant Eagle until a short section beginning on page 132. Finally, some conclusory statements in that section have no citation, while others rely on footnotes that reference documents or testimony that provide absolutely no support for allegedly "undisputed fact" asserted above it *See, e.g.*, Br. at 134 n.429; *id.* at 136 n.437.

McNeil Pharm. v. Hawkins, 686 A.2d 567, 583 (D.C. 1996) (requiring "expert testimony to explain the applicability of statutes where the statute is relied upon as establishing the standard of care"). Instead, an alleged breach of this sort can *only* be established via expert testimony. *Ramage v. Cent. Ohio Emergency Servs., Inc.*, 592 N.E.2d 828, 834 (Ohio 1992). Plaintiffs' purported reliance on their expert reports makes this point all the more clear. Br. at 25.

Yet the *only* expert testimony regarding Giant Eagle's compliance with the DEA's SOM regulations comes from two Giant Eagle experts—a former DEA agent and a practicing pharmacist with extensive industry experience as a pharmacy executive. Both testified that Giant Eagle's SOM system fully complied with DEA regulations. In contrast, despite having spent millions of dollars to retain over 20 experts, Plaintiffs could not persuade one to offer an expert opinion regarding Giant Eagle's SOM program. Plaintiffs literally offer no rebuttal. Their only SOM experts, James Rafalski and Seth Whitelaw, do not even mention Giant Eagle or HBC in their reports.[248] Without such expert testimony, Plaintiff's request for summary judgment must be denied. *See e.g., Kinn v. HCR Manorcare*, 2011 Ohio Misc. LEXIS 13507, at *5-6 (Ohio C.P. Nov. 29, 2011) (denying plaintiff's motion for partial summary judgment because, even assuming that the applicable regulations announced a standard of care, plaintiff failed to present expert testimony establishing defendants breached any such standard).

b. Giant Eagle's "Communications With the DEA" Show That DEA Found Giant Eagle to Be in Compliance With the CSA.

Giant Eagle's communications with the DEA reveal that, following periodic inspections and audits of the HBC Warehouse, the DEA *never* issued an order to show cause, *never* issued any citations, and *never* pursued any enforcement actions against Giant Eagle. *See* Chunderlik

[248] Plaintiffs' expert Craig McCann, an economist, analyzes ARCOS and HBC data in his Report. In contrast to Rafalski and Whitelaw, McCann's "analysis" just looks at data. It is "[n]ot about—about some subject matter conduct by any of the parties." McCann Tr. 89:14-15; 92:10-12 & 129:6-15 ("I'm just serving as a calculator").

Tr. 259:11-23 (Dkt. 1959-24/1975-24); Carlson Tr. 222:24-223:16; Durr Tr. 171:16-22 (Dkt. 1961-20/1976-20); *see also* Mollica Tr. at 60:3-61:3. Rather, during repeated inspections and audits, the DEA found Giant Eagle to be in compliance with the CSA and never penalized the company. Carlson Tr. 200:2-24, 222:24-223:16; Mollica Tr. 60:3-61:3; Prevoznik 30(b)(6) Tr. 129:20-131:23 (explaining that the DEA inspects registrant's monitoring systems during pre-registration and regular audits). For this reason, Giant Eagle and HBC are not listed anywhere in the chart attached to Plaintiffs' motion and are conspicuously absent from the list of Defendants who have admitted their non-compliance to the DEA. Br. at 25 (listing Defendants who have admitted non-compliance); *id* at Attach. (Chart of "Enforcement Actions the DEA Took vs Distributors and Pharmacies").

c. "Internal Documents Concerning SOM" Show Giant Eagle Maintained an Effective Program.

Ample unrebutted evidence—including suspicious order reports, emails, and policies and procedures—confirms the effectiveness of Giant Eagle's SOM system. Emails show that warehouse and corporate employees actively monitored orders and engaged in follow-up investigations. *See, e.g.*, HBC_MDL00090010 (Dkt. 1948-15/1967-15); Ex. 191, Nov. 19, 2013 Email (HBC_MDL00132864). Other documents—some of which Plaintiffs cite in their motion—show efforts to investigate flagged orders and prevent diversion.[249] *See, e.g.*, HBC_MDL00039223 (Dkt. 1948-13/1967-13) & HBC_MDL00058099 (Dkt. 1948-14/1967-14); *see also* Ex. 192, Nov. 25, 2013 Email (HBC_MDL00094599). The record also makes clear that Giant Eagle fulfilled its duties to prevent diversion at its pharmacies where, for example, the

[249] The due diligence record is inherently incomplete because of elapsed time and significant personnel turnover at Giant Eagle. Yet the remaining documentation and related testimony show that Giant Eagle's investigations were regular, consistent, and thorough. *See, e.g.*, Millward Tr. 100:11-101:2 (Dkt. 1968-3/1981-20) ("When there's a flag, it get investigated"); *id*. 183:22-185:8; *see also* Wright Tr. 143:2-12 (testifying, as authorized by the DEA, that there is no "regulatory requirement to document due diligence" on orders).

company promised to support the judgment of any pharmacist who, "after performing required due diligence and in the exercise of his/her professional judgment… determines that a prescription should not be filled." *See* Ex. 193, Giant Eagle Controlled Substance Dispensing Guideline (HBC_MDL00180760 at 180763); *see also, e.g.*, Ex. 194, Aug. 18, 2011 Email re Controlled Drug Procedures (HBC_MDL00180816-824); Ex. 195, Giant Eagle Fraud Waste and Abuse Compliance Manual (HBC_MDL00043955).[250]

2. Giant Eagle Had an Effective System to Both Identify and Prevent Potential Diversion.

With no expert testimony, no adverse actions by the DEA, and nothing to counter the ample documentary evidence showing that Giant Eagle had a compliant and effective SOM program, Plaintiffs cannot establish that Giant Eagle did anything wrong. Instead, Plaintiffs have moved for summary judgment against Giant Eagle in sole reliance on the unsupported assertions of their lawyers in their summary judgment brief that Giant Eagle violated the CSA. But these assertions are no substitute for evidence and, as such, they cannot be used to support a motion for summary judgment. This is especially true when the undisputed evidence supports the opposite conclusion—*i.e.*, that Giant Eagle's SOM system exceeded regulatory requirements and was highly effective at preventing diversion.

a. Plaintiffs Ignore Evidence That Giant Eagle Had Effective SOM policies and Procedures Prior to 2014.

The earliest written SOM policy that Giant Eagle produced in this litigation is dated 2014. Plaintiffs, however, fail to mention substantial evidence showing that the 2014 policy

[250] Plaintiffs also rely on documents in a misleading manner. For example, while Giant Eagle admitted in interrogatory responses that HBC provided no "educational, information and/or other programs to any Customer and/or pharmacy dispenser that it owns and/or controls," it also stated that Giant Eagle "has provided numerous training programs, continuous education opportunities, and policies with the goal of minimizing and eliminating the diversion of controlled substances." *HBC Serv. Co.'s Supp. Answers to Pls.' First Set of Interrogs. to HBC*, Mar. 4, 2019, Interrog. Resp. No. 23, at 42-43 (Dkt. 1948-3/1967-3).

replaced SOM policies and procedures going back to the opening of HBC's controlled substance facility in 2009. *Compare* Br. at 133, *with* Rogos Tr. 132:16-133:23 (Dkt. 1970-8/1984-1) (explaining that the 2014 policy was based on a pre-existing policy); Durr Tr. 64:19-69:21.

Giant Eagle's 2014 plan to seek accreditation as a Verified-Accredited Wholesale Distributor prompted it to create an entirely new set of policy documents covering dozens of issues. *See, e.g.*, Rogos Tr. 70:4-71:8 & 132:16-25. But this does not mean that predecessor policies did not exist—only that they were not formally archived after Giant Eagle drafted revised policies. Ashley Tr. 252:5-12 (testifying, as authorized by the DEA, that "how records [related to suspicious order monitoring] are kept" is up to the "discretion of distributors"); Rogos Tr. 132:16-133:17 (testifying that the prior to 2014, the relevant policies were maintained in a notebook at the HBC facility). That Giant Eagle had written policies prior to 2014 is confirmed by Giant Eagle employees, who informally retained some of these outdated policies in their files. *See, e.g.*, Ex. 196, 2009 HBC Pharmacy Operations and Procedures (HBC_MDL00189056); Ex. 197, Pharmacy Hand-Off Procedure (HBC_MDL00189086); Ex. 198, Pharmacy Palletizing Procedure (HBC_MDL00189088).

In any event, the DEA has made clear that a written policy is not necessary. As the DEA's Rule 30(b)(6) witness, Thomas Prevoznik explained that "[w]hat matters is do you have an effective means to safeguard against diversion" and conceded that the DEA regulations *do not* require "a written policy with respect to suspicious order monitoring." Prevoznik 30(b)(6) Tr. 358:10-359:2; *see also* 21 C.F.R. § 1301. The DEA regulations require that Giant Eagle operate an effective SOM system—not keep copies of outdated policies.[251]

[251] As further evidence that Giant Eagle had a SOM system before 2014, Plaintiffs themselves concede that, "[i]n December 2013, HBC reported its only suspicious order" for the period between November 2009 to October 2014 (the "2013 Order"). Br. at 136. This pre-2014 suspicious order report undermines Plaintiffs' claim that there was

b. Plaintiffs Ignore Unrebutted Proof That Giant Eagle Was Not a Source of Diversion.

As the DEA's corporate designee, Thomas Prevoznik explained that "however [registrants] design [their SOM system], they need to get the big picture so that they truly know what is their customer doing." Prevoznik 30(b)(6) Tr. 181:23-182:1. Giant Eagle knew what its only customer was doing at all times because Giant Eagle was its own customer. As such Giant Eagle knew, as both distributor and customer, that its pharmacies were not diverting controlled substances.

Comparing pharmacies' controlled drug prescriptions to overall prescriptions, the DEA views a ratio of 20 percent or less as a benchmark suggesting a lack of diversion. *See* Wright Tr. 260:4-18 (confirming that "it was common for legitimate pharmacies to have a ratio of approximately 20 percent of controlled to 80 percent noncontrolled"); *id.* 300:15-301:7; Rannazzisi Tr. 453:13-454:8 (Dkt. 1969-21/1983-18). Giant Eagle's ratio across pharmacies in the Counties during the relevant period was less than 10 percent. Am. Kinsey Rpt. ¶ 76 & Ex. H. Thus, while Plaintiffs aggregate the number of individual pills and milliliters (called "units" in Plaintiffs' motion) to make it appear that Giant Eagle distributed "large volumes of controlled substances," in truth, orders shipped from Giant Eagle's warehouse—all of which filled legitimate prescriptions at Giant Eagle pharmacies—were consistent with the pharmacies' *overall* business in the Counties. As further proof that its procedures were thwarting diversion, Giant Eagle's market share of HCP prescriptions was significantly *less* than its market share for other controlled and non-controlled medications.[252] Am. Kinsey Rpt. ¶ 78. Equally telling,

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no meaningful system prior to August 2014. In reality, Giant Eagle had policies and procedures that could effectively identify and report suspicious orders.

[252] As previously noted, HBC's MME market share was less than 1 percent in both Counties, showing that even when not compared with Giant Eagle's overall business, Plaintiffs' claim that these aggregated "units" constituted "large volumes" is disingenuous. *See* HBC Mem. at 15-16; *see also* Kinsey Tr. 214:7-10 (1963-18/1979-11) (describing HBC's market share in the Counties as "tiny. It's miniscule").

Plaintiffs do not identify *even one* suspect prescription that came from Giant Eagle's HBC warehouse, despite ample opportunity to do so. HBC Mem. at 14-15.

3. Giant Eagle's Threshold System Was a Redundant Additional Control That Proved Giant Eagle's Integrated Controls Against Diversion Were Sufficient for its Self-distribution, HCP-only Operation.

Putting aside that the DEA has *never* required a threshold system, the record shows that Giant Eagle had SOM policies and procedures in place when it opened the HBC warehouse in 2009. *See* Prevoznik 30(b)(6) Tr. 108:23-109:4 (agreeing that the "DEA did not require that a distributor to use a particular calculation or algorithm to identify excessive purchases of controlled substances"); Wright Tr. 344:5-345:8 (Dkt. 1972-13/1985-25). From day one, Giant Eagle had its warehouse employees closely monitor orders and, because these employees were "attuned to the normalcies" of orders coming from Giant Eagle pharmacies, if they saw aberrations, they would bring it to the attention of warehouse supervisors who would begin an investigation. Durr Tr. 90:8-91:7 & 92:12-93:8.

On top of that, Giant Eagle's corporate headquarters closely monitored orders to ensure that there were no unusual fluctuations in product purchases or "out of the norm patterns in that process." Carlson Tr. 142:11-143:3; Durr Tr. 92:12- 93:16; Tsipakis 30(b)(6) Tr. 99:1-18. And Giant Eagle's "corporate team had full visibility of [HBC's] inventory at all times and could see if there was any fluctuation whatsoever." Durr Tr. 86:11-23; *see also* Heiser Tr. 19:14-20:8 (Dkt. 1962-27/1978-7) ("We also had corporate oversight of both the stores and the warehouse. The warehouse had buyers that were monitoring from a human perspective the orders that were placed by the stores and also the orders that were placed to the manufacturers.").

During its audits and inspections, the DEA found that these policies and procedures were compliant with the CSA. This is not surprising given that Giant Eagle maintained control over

its product from the warehouse to the pharmacy, and could "intercept, retrieve, [or] quarantine product" throughout the distribution process.[253] Tsipakis 30(b)(6) Tr. 173:10-174:8. While Plaintiffs suggest that they know more than the DEA about "meaningful" compliance, they do not. *See* Br. at 132. And the only experts in this litigation that say anything about Giant Eagle's compliance with the CSA—Sandra Kinsey and Matthew Greimel—both opine that Giant Eagle's anti-diversion program complied with the CSA in all respects.[254] Am. Kinsey Rpt. 9-10; Greimel Rpt. 13.

J. Discount Drug Mart

Plaintiffs seek "partial summary adjudication" against Defendant Discount Drug Mart, Inc. ("DDM") based on DDM's perceived failure to identify "suspicious orders" under the Controlled Substances Act ("CSA"). For the reasons that follow, Plaintiffs cannot demonstrate that DDM violated the CSA, and Plaintiffs' motion must be denied.

1. DDM's Distribution of Prescription Opioids.

Plaintiffs raise no claim concerning DDM's actions as a *pharmacy*. *See* Dkt. 1203 – Opinion and Order at 2. Instead, Plaintiffs' claims against DDM relate to its conduct *as distributor* of prescription opioids to *its own pharmacies*. *Id.* Implicit therein is the fact that DDM did *not* distribute a single opioid to third parties — no rogue internet pharmacies, rogue pill mills, or rogue pain clinics. *See* Ex. 200 – DDM's Answers to Rog. Nos. 17, 24; Briscoe Tr.

[253] DEA representatives have also testified that it does not matter if a SOM system is automated or manual, making Plaintiffs' claim that HBC did not have an automated system to stop orders entirely irrelevant. Prevoznik 30(b)(6) Tr. 180:12-15.

[254] Plaintiffs only effort to rebut Giant Eagle's experts is a footnote claiming Mr. Greimel bases his opinions, "to some extent," on an erroneous conclusion regarding the shipping requirement. Br. at 139 n.448. Plaintiffs provide no support for this claim and did not file a *Daubert* motion to restrict Mr. Greimel's testimony on this or any other basis. Plaintiffs also claim Mr. Greimel "did not review what HBC actually did." *Id.* Mr. Greimel's report and testimony show that he reviewed copious evidence about Giant Eagle's policies and its actions. Greimel Rpt. App. B; Ex. 199, Greimel Tr. 126:22-127:14. Plaintiff do not mention Ms. Kinsey except to erroneously rely on her Report to support their general arguments about SOM systems. Br. at 18.

22:4-8, 51:17-19 (Dkt. 1959-11/1975-11); Ratycz Tr. 100:15-20 (Dkt. 1970-2/1983-20). In fact, Plaintiffs' own expert, Craig McCann, determined that DDM distributed ***less than 0.9%*** of the opioids legally distributed to the Plaintiff counties. *See* McCann Rpt., Appx. 9 at 3779, 3849 (Dkt. 2000-14/1993-13).

2. No DEA Enforcement Actions or Criminal Convictions.

Perhaps more importantly, DDM has *not* been the subject of a DEA enforcement action associated with DDM's opioid distributions, nor has DDM ever been charged with, much less convicted of, any crimes relating to opioids. Likewise, Plaintiffs do *not* allege that DDM's pharmacies committed any wrongdoing. *See* Dkt. 1203 – Opinion and Order at 2. If DDM's pharmacies did not commit any wrongdoing, it is unclear how DDM's shipments of perceived "suspicious orders" to those same pharmacies can form the basis for any claim of wrongdoing against DDM.

3. No Expert Testimony Offered Against DDM.

It should further be noted that other than Dr. McCann (who is an *economist* that offered no *substantive* opinions in support of Plaintiffs' claims against any Defendant – *see, e.g.*, McCann Tr. 149:3-150:9, *none of Plaintiffs' expert witnesses opine that DDM violated the CSA* or committed any wrongdoing in support of Plaintiffs' claims. Indeed, the record is replete with Defense expert reports (cited herein by other Defendants) that wholly dispel Plaintiffs' self-serving interpretations of the requirements and obligations set forth in the CSA for registrants such as DDM.

4. Plaintiffs Have Not Satisfied the Causation Requirement.

Finally, even assuming that Plaintiffs satisfy their burden of proof in demonstrating that DDM violated requirements as to suspicious order monitoring systems (which they cannot), Plaintiffs' motion should be denied for another reason: Plaintiffs are still required to prove the

requisite causal connection between these perceived violations and Plaintiffs' damages – *which Plaintiffs cannot do*. In order to accomplish this (as to DDM), Plaintiffs *must further prove that*:

- DDM's suspicious orders were diverted;
- These diverted DDM prescriptions led to opioid abuse and addiction by certain individuals in Cuyahoga and Summit Counties;
- The opioid addiction of these certain individuals (stemming from DDM distributed opioids) further led to illicit drug use (heroin, illicit fentanyl, crack cocaine, crystal methamphetamine, etc.) by these same opioid-addicted individuals;
- This use of illicit drugs by these opioid-addicted individuals caused damages to Cuyahoga and Summit Counties; and
- These damages attributable to DDM can be proven to a *reasonable degree of certainty* as required by Ohio law.[255]

Plaintiffs can point to absolutely no *evidence* to satisfy this *requisite* causal chain.

Plaintiffs are clearly cognizant of this fatal defect, and hope to bypass the traditional causation requirements by improperly contending that the perceived violations satisfy Plaintiffs' burden of proof on causation – which they do not. For this reason, as well as those outlined above, Plaintiffs' motion should be denied as a matter of law as to DDM.

K. Other Defendants

Plaintiffs have presented no argument or evidence to meet their summary judgment burden as to numerous "Defendants," and summary judgment must be denied as to such excluded Defendants for that reason alone.

[255] Ohio law is clear that where "causation is premised on the total cumulative" effect of numerous actors, a defendant cannot be held liable unless its conduct taken individually "'had a *substantial* impact on the total.'" *Schwartz v. Honeywell Internatl., Inc.*, 153 Ohio St.3d 175, 180-181, 102 N.E.3d 477 (2018) (emphasis added). Given DDM's *de minimus* market share, Plaintiffs cannot meet this heavy burden.

While Plaintiffs' motion vaguely references seeking summary adjudication as to "Defendants" for alleged CSA violations, Sections II.A-N of Plaintiffs' supporting memorandum addresses certain specific Defendants, but neither the motion nor the memorandum provides any argument or related evidence as to numerous other Defendants ("excluded Defendants"[256]). Moreover, the Conclusion of the memorandum lists specific Defendants against whom Plaintiffs request judgment as a matter of law for alleged CSA violations, but omits all other Defendants from that list. *See* Memorandum at 143. Plaintiffs therefore do not seek summary adjudication on Defendant-specific CSA violations as to those excluded Defendants because they fail to inform the Court of any basis for their motion as to such excluded Defendants, and have not identified evidence to demonstrate they are entitled to summary judgment against any of them. Plaintiffs' motion must be denied with respect to such excluded Defendants for that reason alone. *See Celotex*, 477 U.S. at 323 (party seeking summary judgment "always bears the initial responsibility of informing the district court of the basis for its motion").

CONCLUSION

For all of these reasons, Plaintiffs' motion should be denied.

[256] The excluded Defendants include: Anda, Inc.; H. D. Smith, LLC, H. D. Smith Holdings, LLC, and H. D. Smith Holding Company ("H. D. Smith"); Henry Schein, Inc. and Henry Schein Medical Systems, Inc. (collectively, "Henry Schein"). Noramco, Inc., which is listed as one of the Manufacturing Defendants in Plaintiffs' Complaints, is also one of the excluded Defendants. As explained in the Manufacturer Defendants' separate opposition, Plaintiffs failed to present evidence that Noramco engaged in any wrongful conduct that might give rise to liability.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 31st day of July, 2019, a notice of the foregoing has been served via CM/ECF to all counsel of record, and copies have been served on the same by email.

/s/ Katherine M. Swift
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